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Thapliyal et al.

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(54) **METHODS FOR IMAGING AND ABLATING BODY TISSUE**

(71) Applicant: **VytronUS, Inc.**, Sunnyvale, CA (US)

(72) Inventors: **Hira V. Thapliyal**, Los Altos, CA (US); **David A. Gallup**, Alameda, CA (US); **James W. Arenson**, Woodside, CA (US); **John Paul Mohr, III**, Aptos, CA (US); **Tim Proulx**, Santa Cruz, CA (US); **Robert A. Brommer**, Fremont, CA (US)

(73) Assignee: **VytronUS, Inc.**, Sunnyvale, CA (US)

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(51) **Int. Cl.**
A61B 8/00 (2006.01)
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(52) **U.S. Cl.**
CPC ***A61B 8/4494*** (2013.01); ***A61B 8/0883*** (2013.01); ***A61B 8/12*** (2013.01);
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(58) **Field of Classification Search**
CPC A61B 17/320068; A61B 2017/320069; A61B 2018/00023; A61B 2090/3782;
(Continued)

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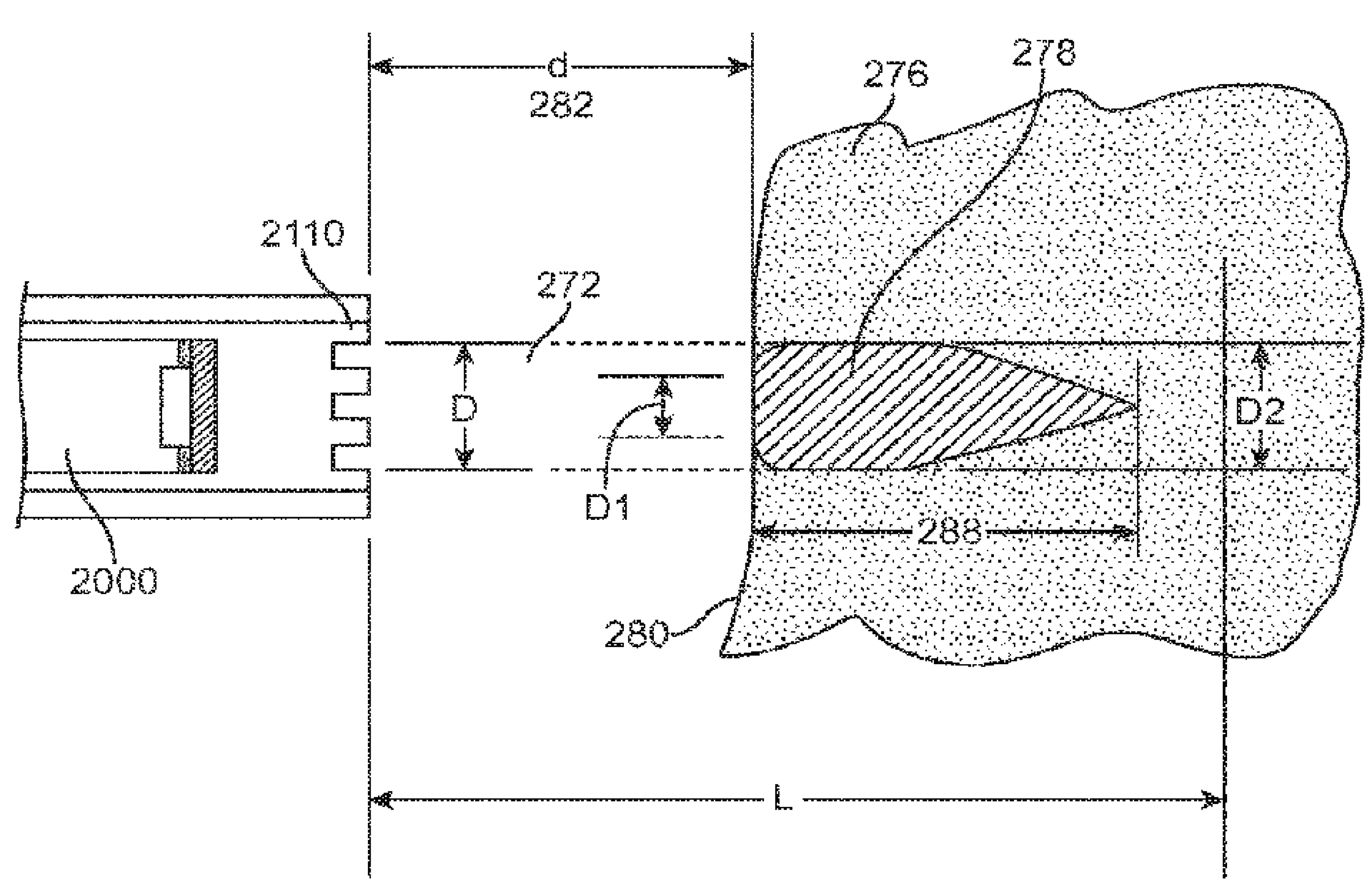
Primary Examiner — Ruth S Smith
(74) *Attorney, Agent, or Firm* — The Mueller Law Office, P.C.

(57) **ABSTRACT**

A method for creating a transmural lesion in tissue includes positioning a distal portion of a catheter near the tissue, where an ultrasound transducer is attached to the distal portion and is operatively coupled to a console and processor. The tissue is imaged by energizing the ultrasound transducer at a first power level to produce an ultrasound beam, where the imaging determines a thickness of the tissue, and a gap distance between the ultrasound transducer and the tissue. The tissue is ablated by energizing the ultrasound transducer at a second power level to produce the ultrasound beam. Energy delivered to the tissue during the ablating is controlled, using the processor, where the processor adjusts a speed of the ultrasound beam moving across the tissue based on the thickness and gap distance, to create the transmural lesion.

21 Claims, 10 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/620,287, filed on Nov. 17, 2009, now Pat. No. 8,475,379.

(60) Provisional application No. 61/115,403, filed on Nov. 17, 2008.

(51) **Int. Cl.**

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A61B 17/32	(2006.01)
A61B 18/00	(2006.01)
A61B 90/00	(2016.01)

(52) **U.S. Cl.**
CPC ***A61B 8/445*** (2013.01); ***A61B 17/320068*** (2013.01); ***A61N 7/022*** (2013.01); *A61B 2017/320069* (2017.08); *A61B 2018/00023* (2013.01); *A61B 2090/3782* (2016.02)

(58) **Field of Classification Search**
CPC A61B 8/0883; A61B 8/12; A61B 8/445; A61B 8/4494; A61N 7/022
See application file for complete search history.

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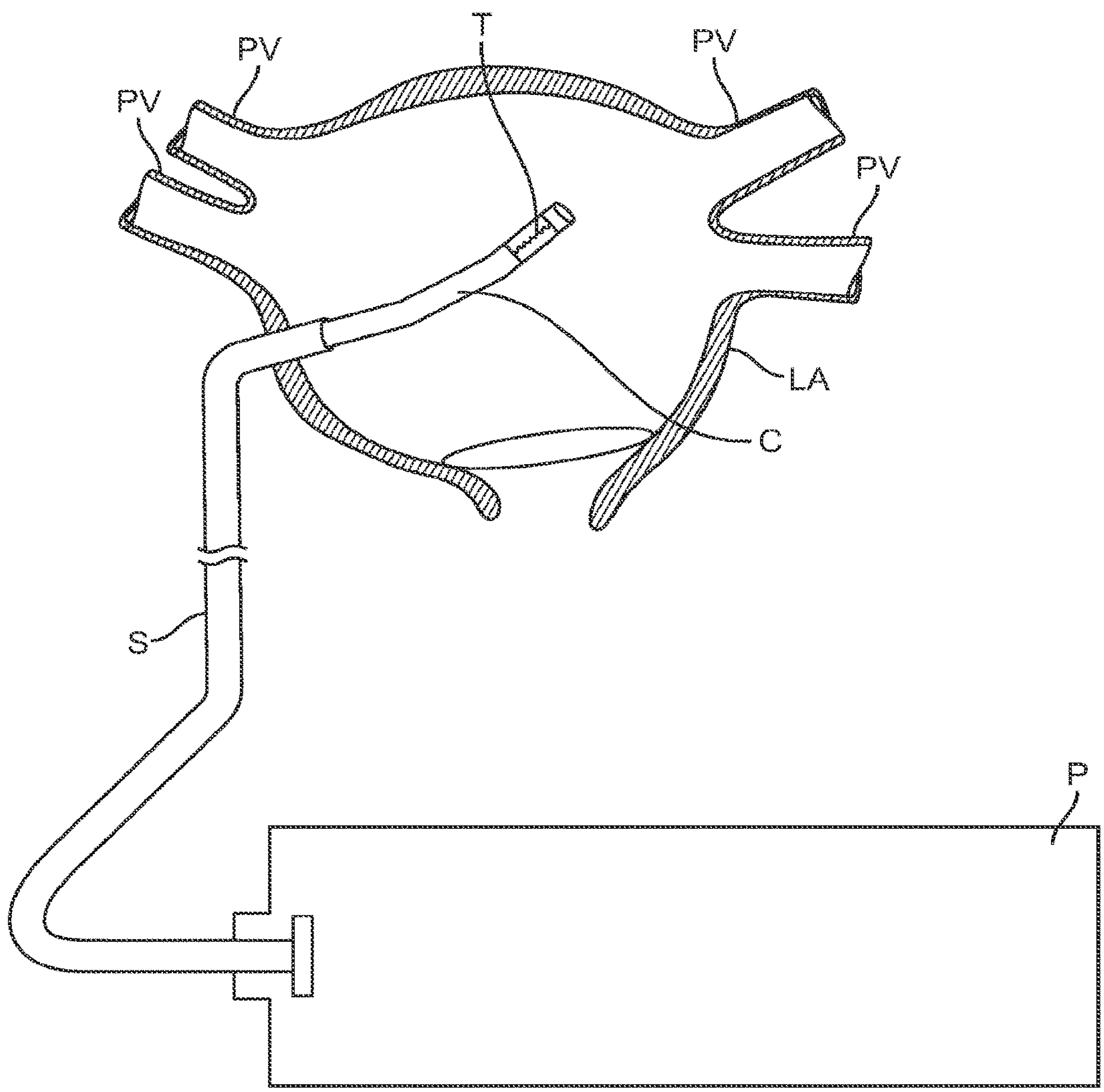


FIG.1A

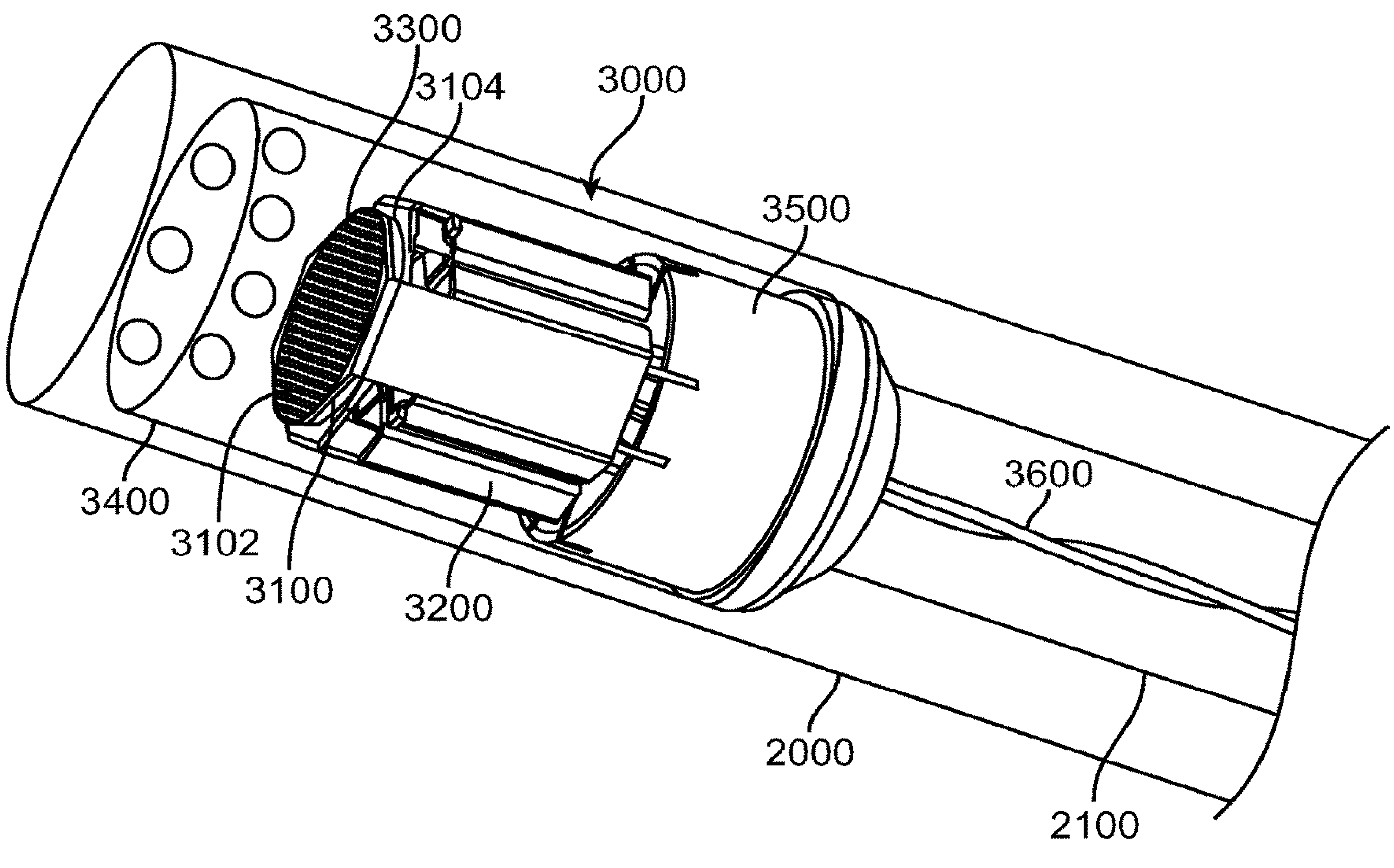


FIG. 1B

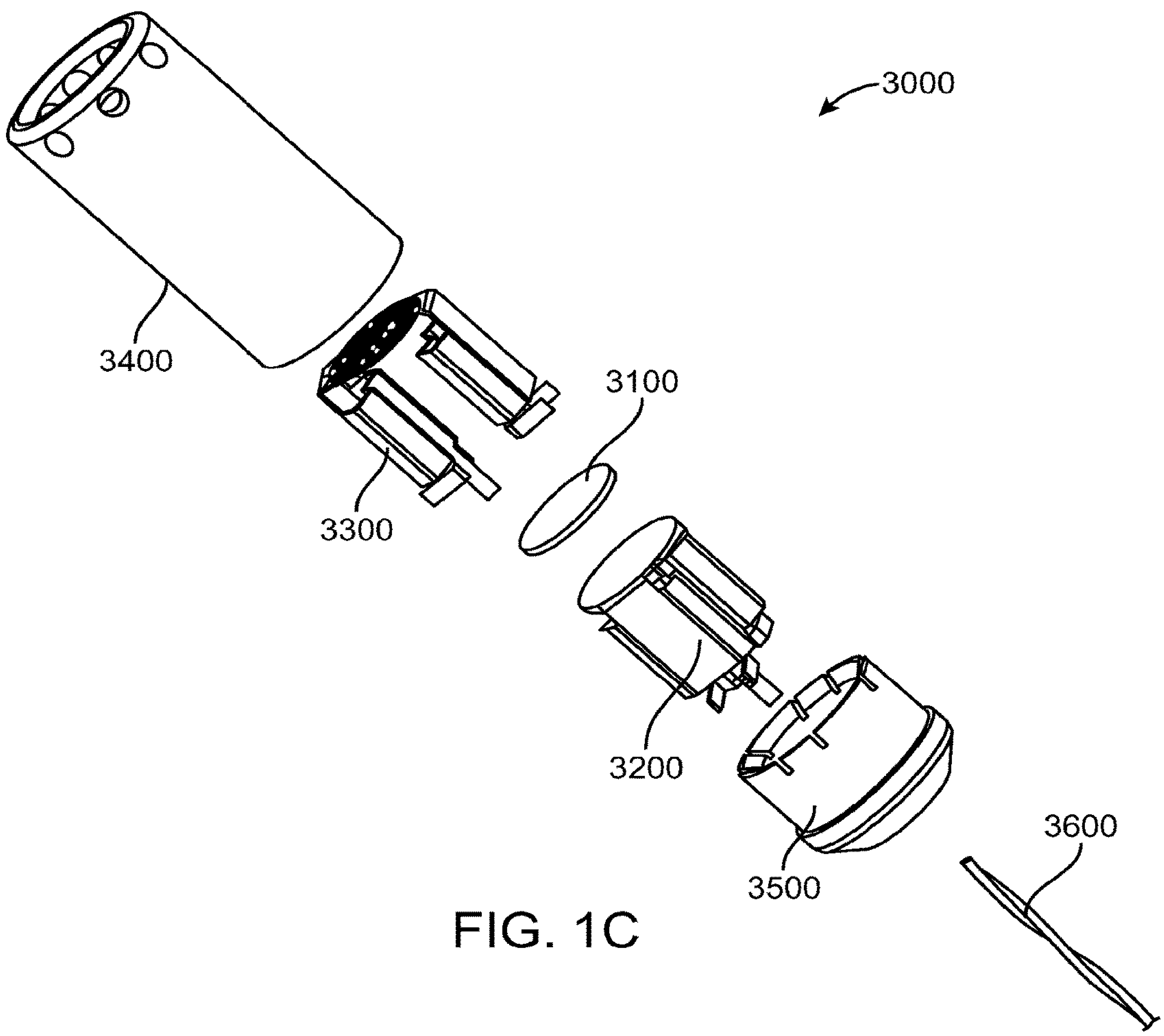


FIG. 1C

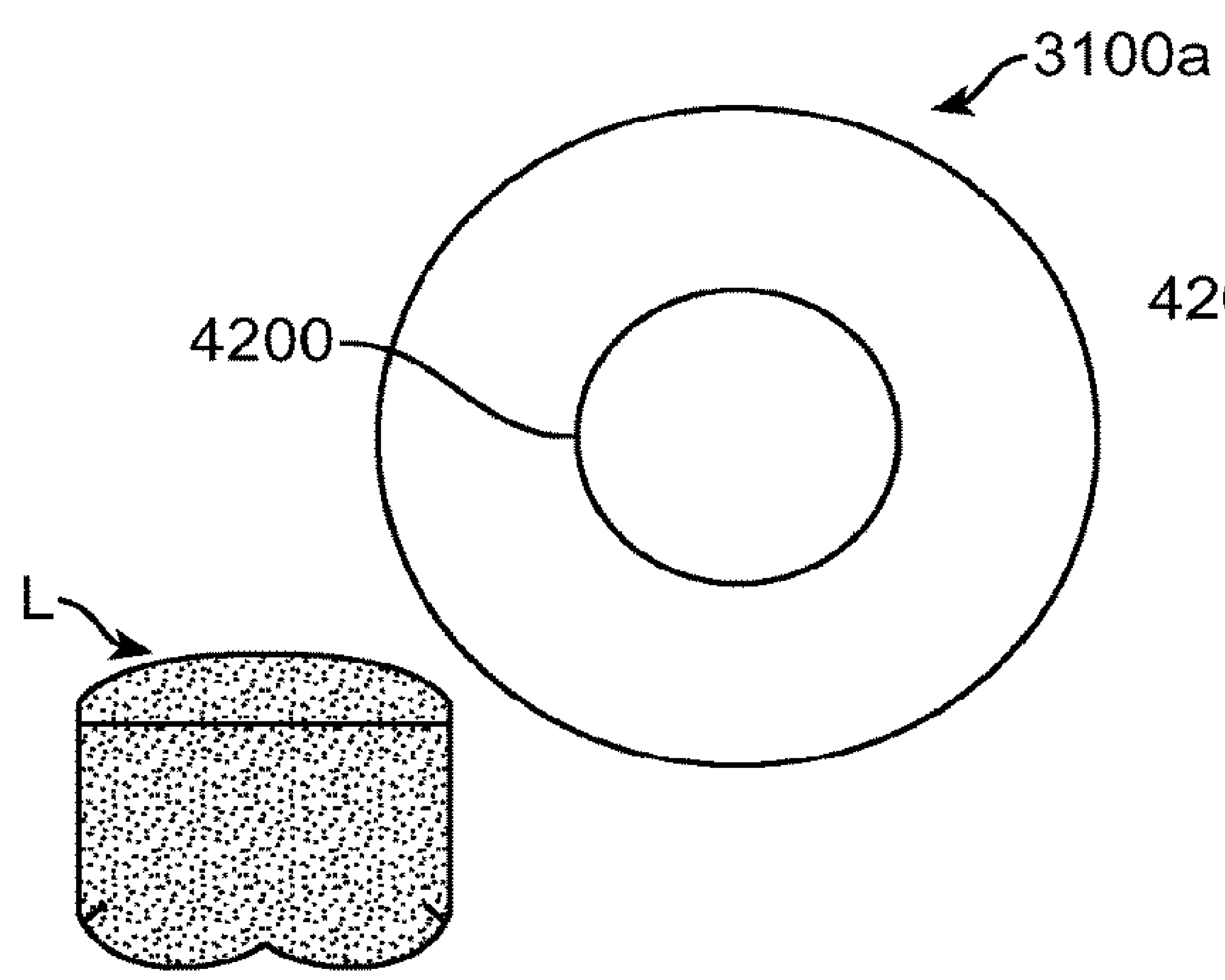
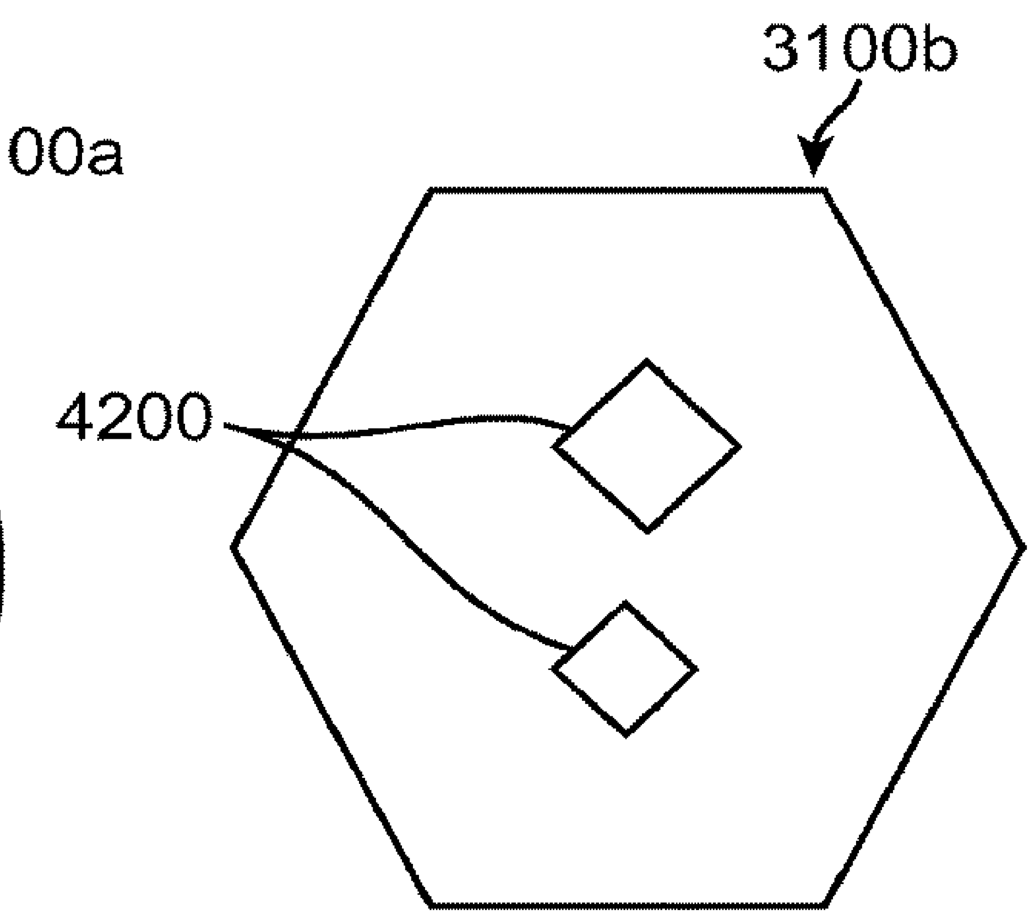


FIG. 2A



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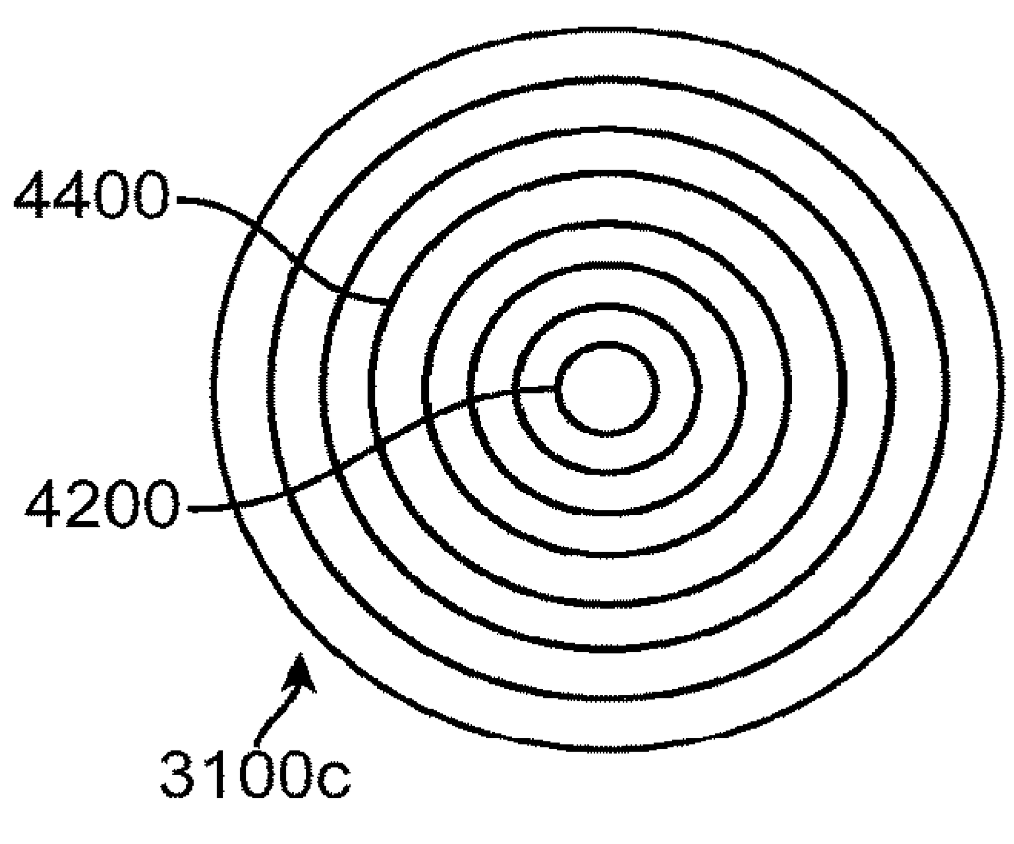

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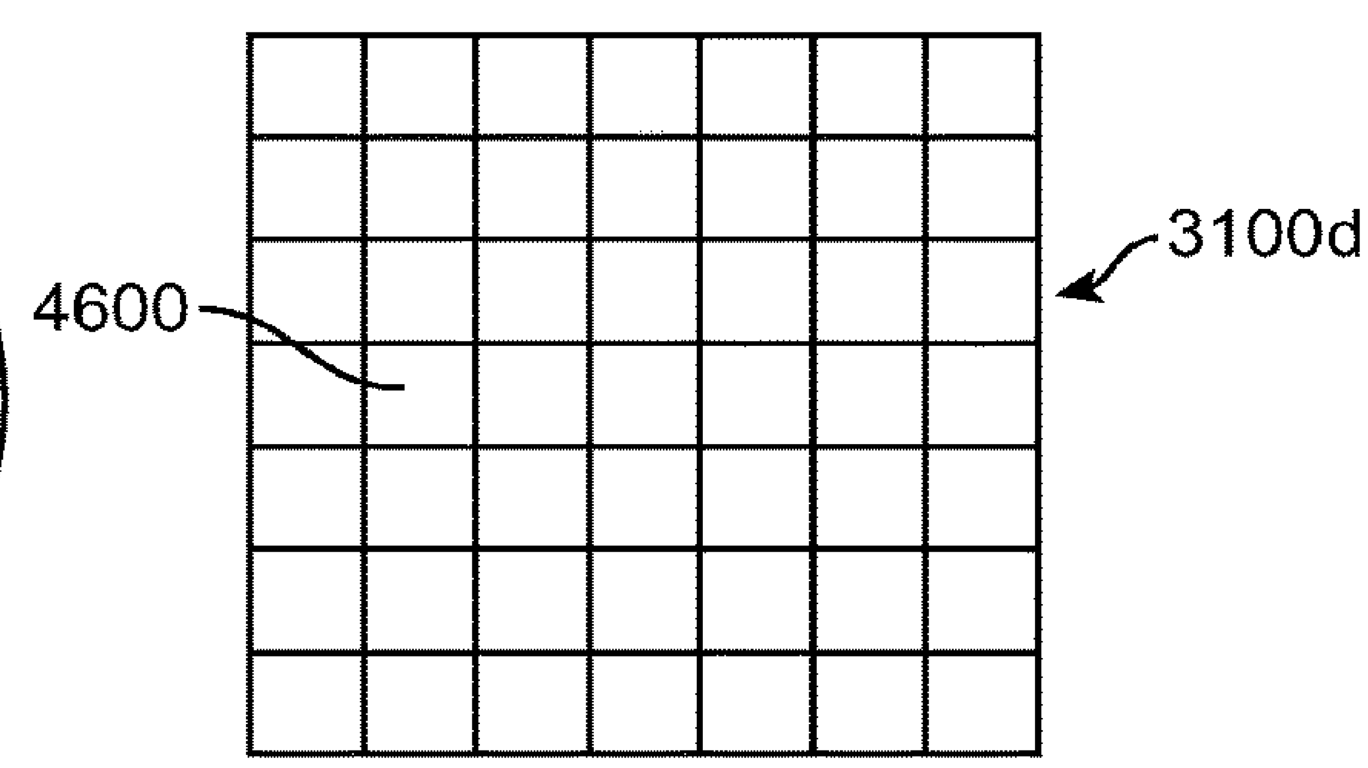

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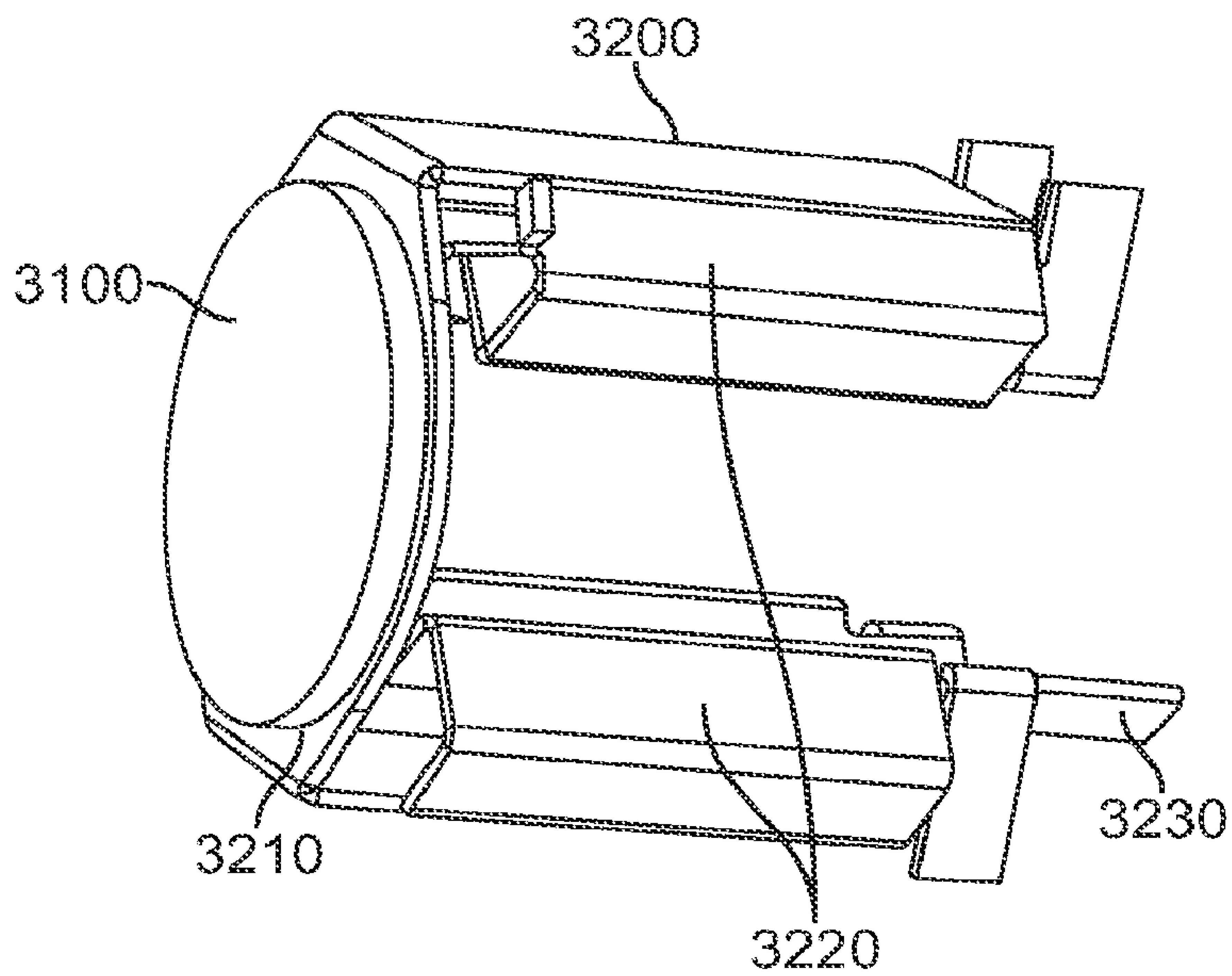
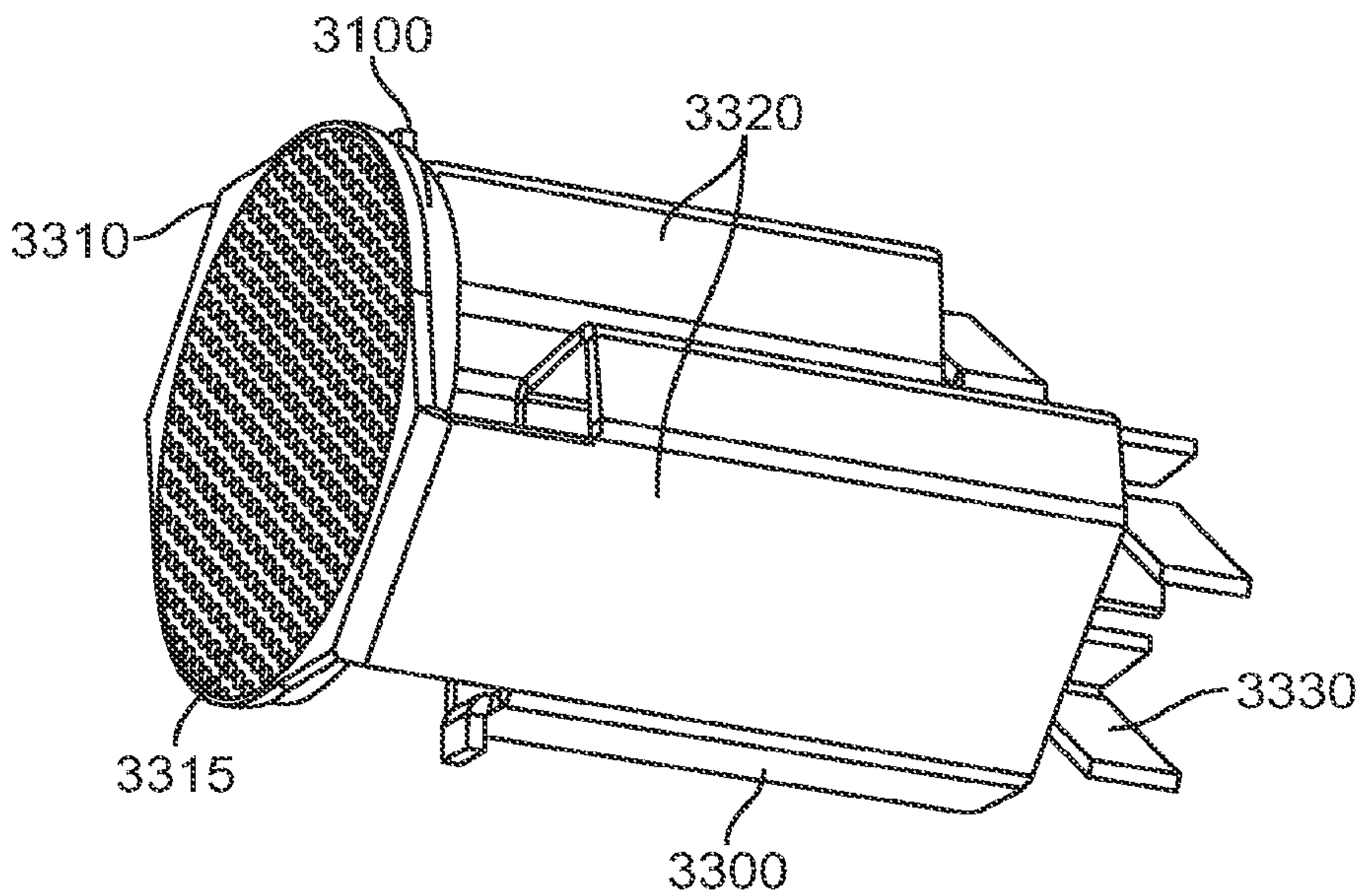


FIG. 3



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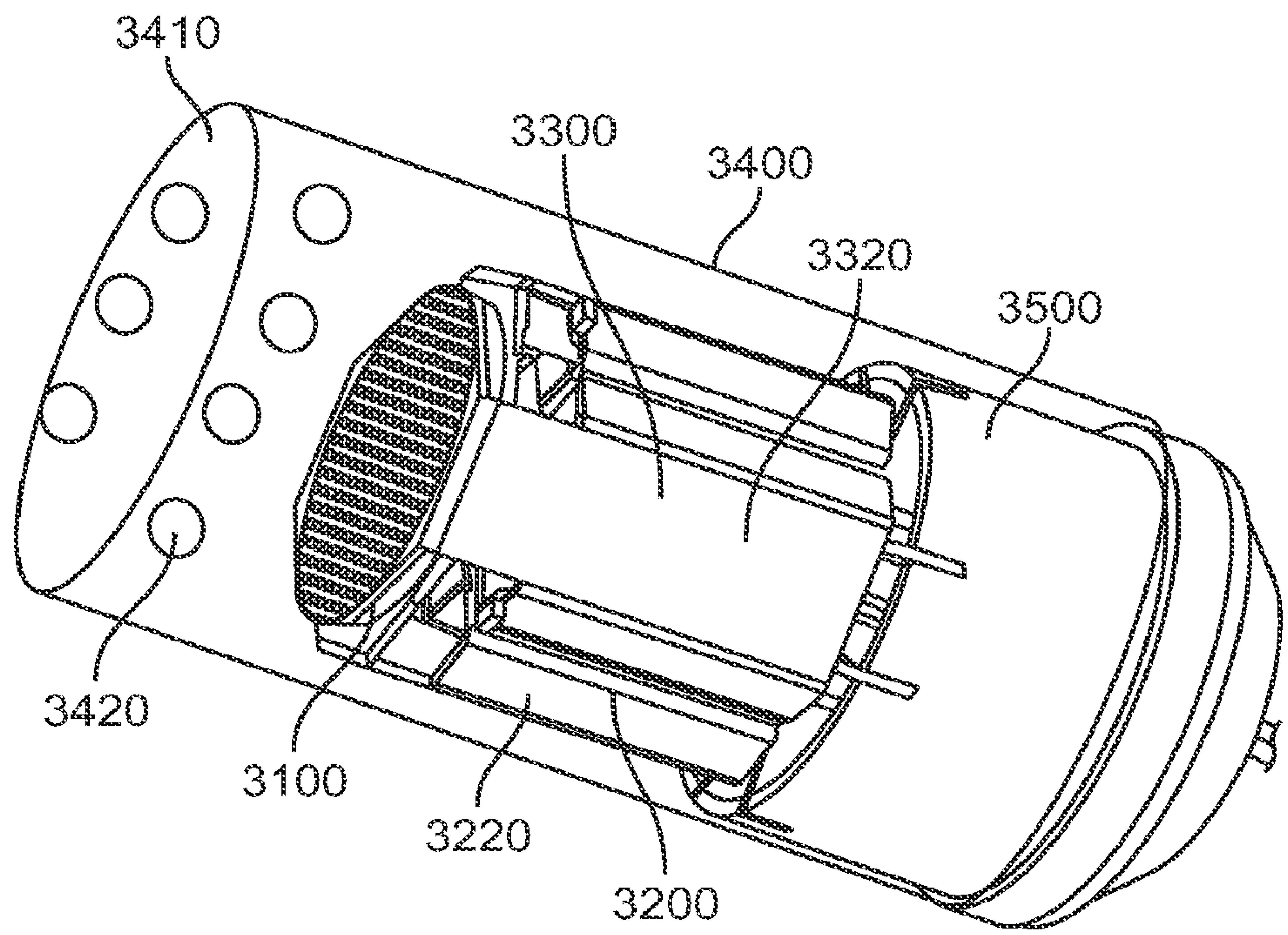

FIG. 5

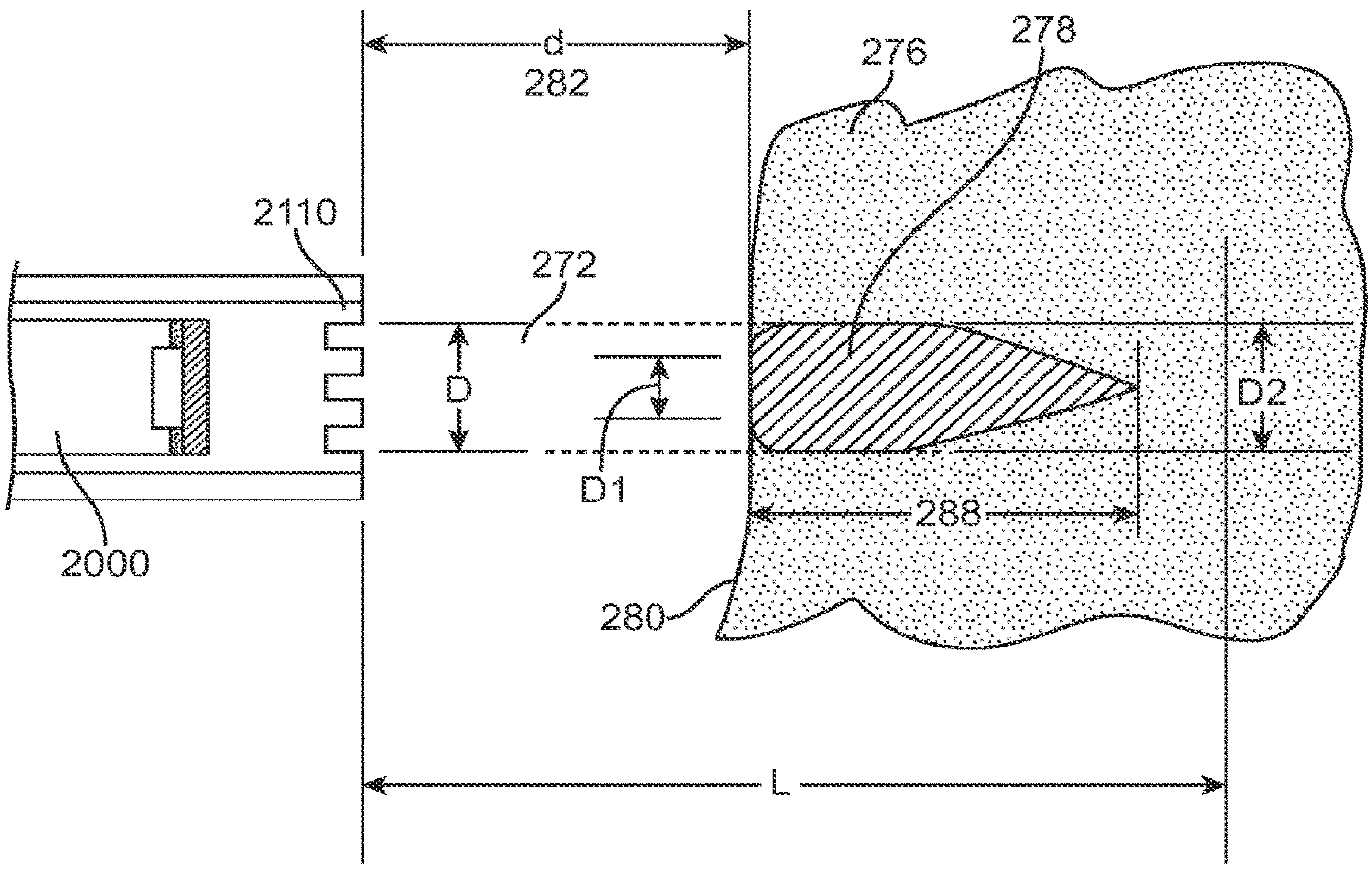

FIG. 6

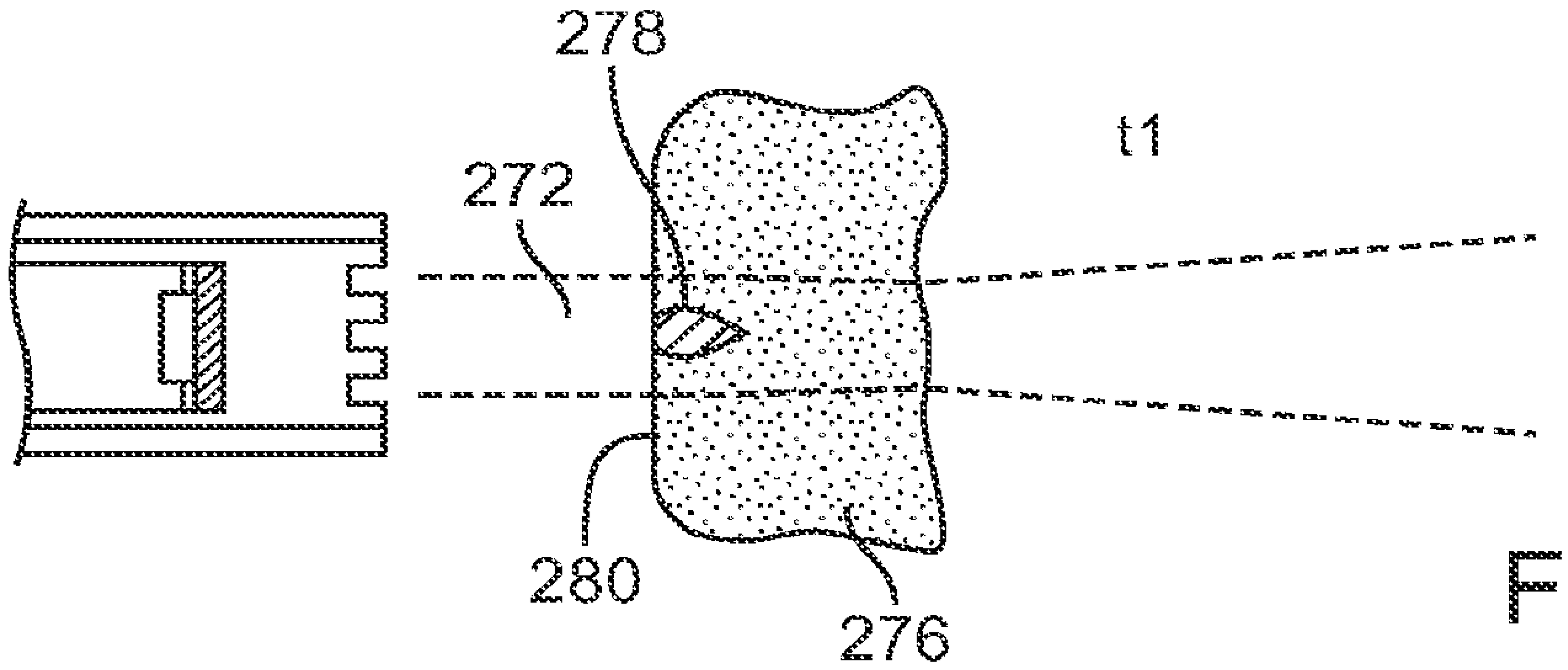

FIG. 7A

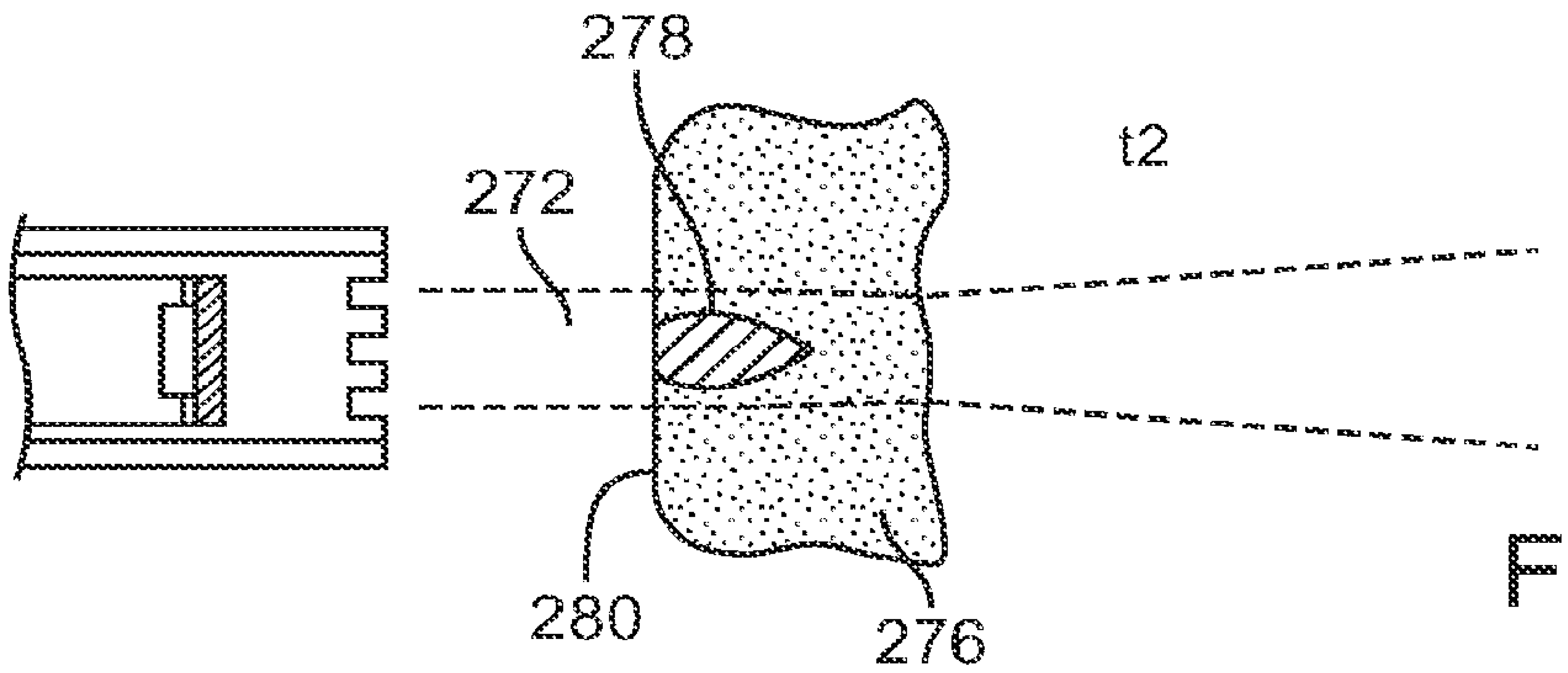

FIG. 7B

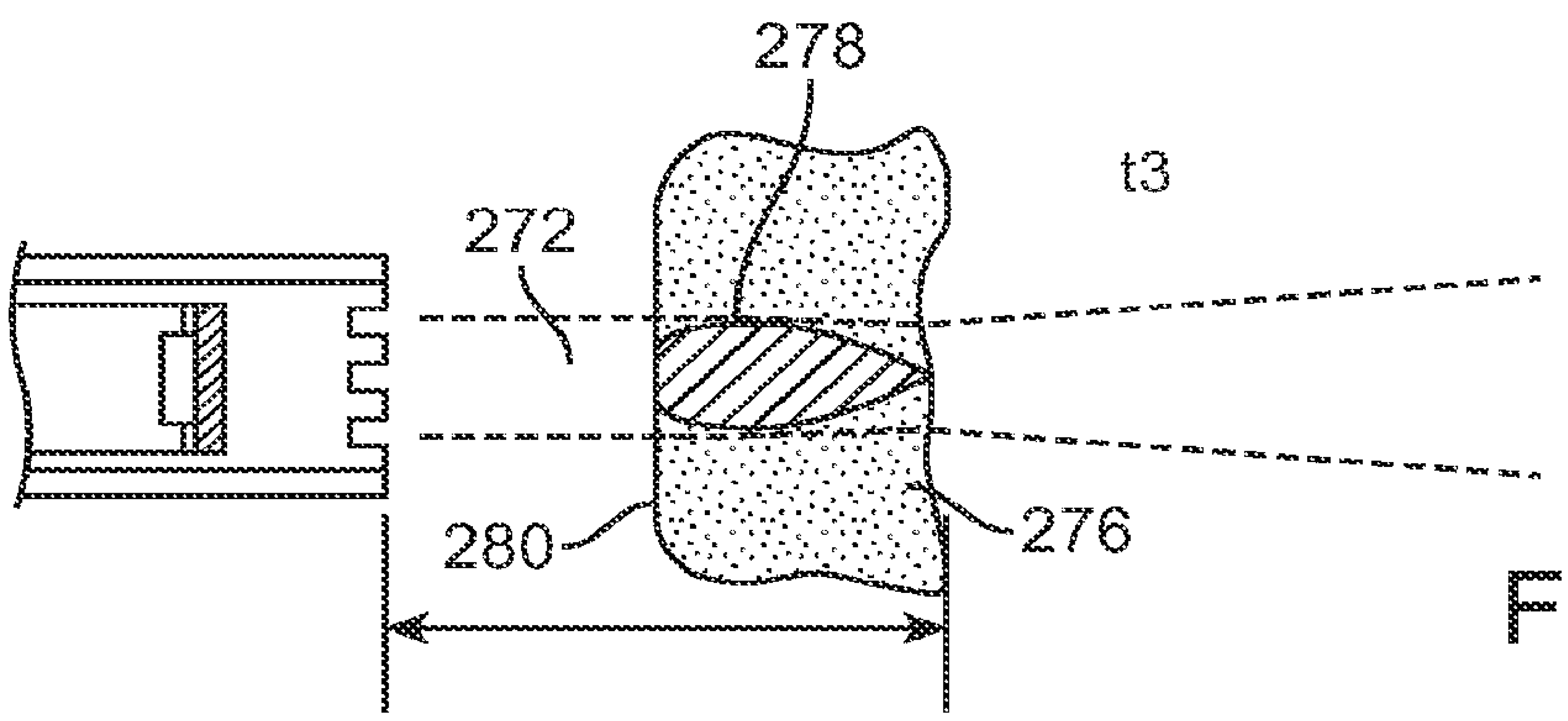

FIG. 7C

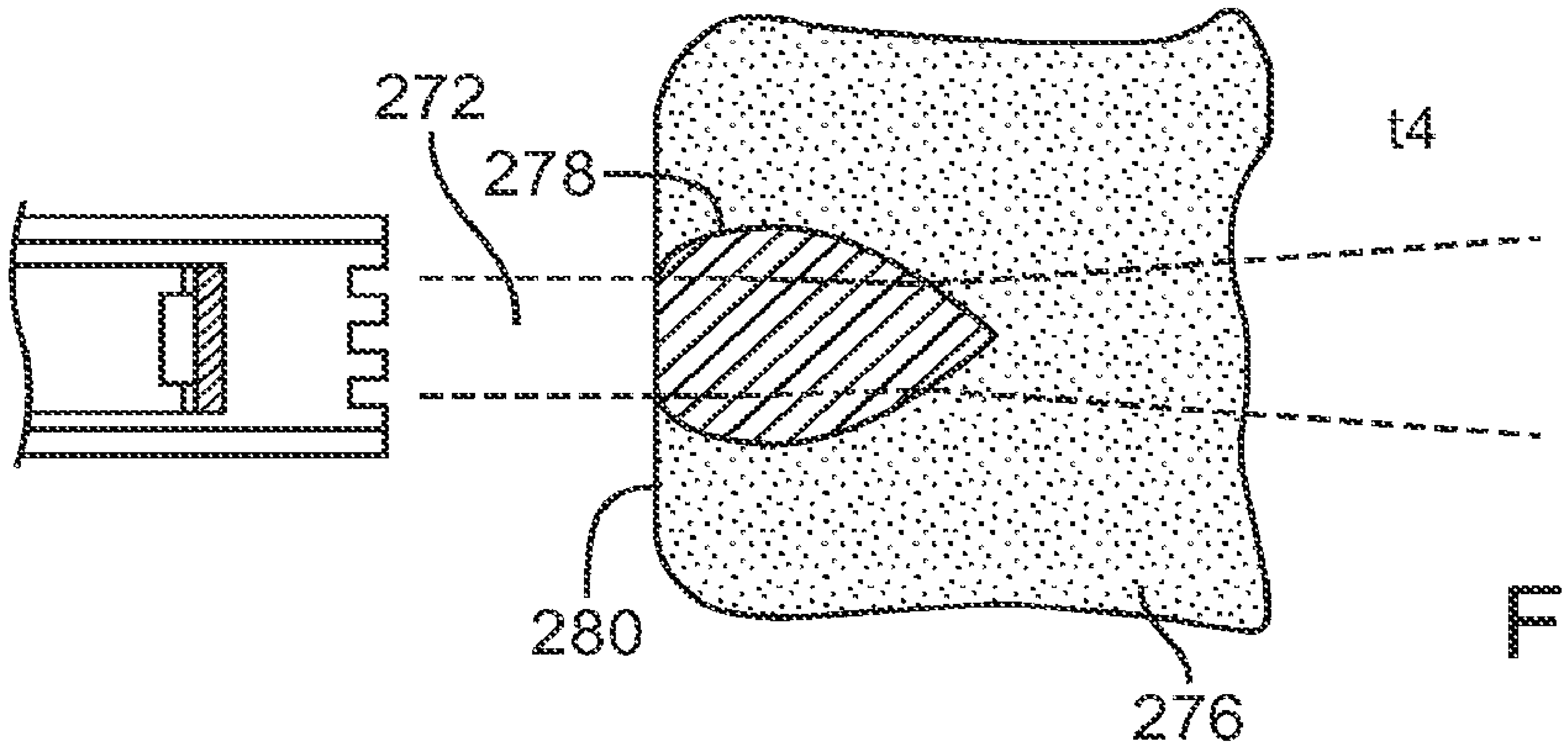

FIG. 7D

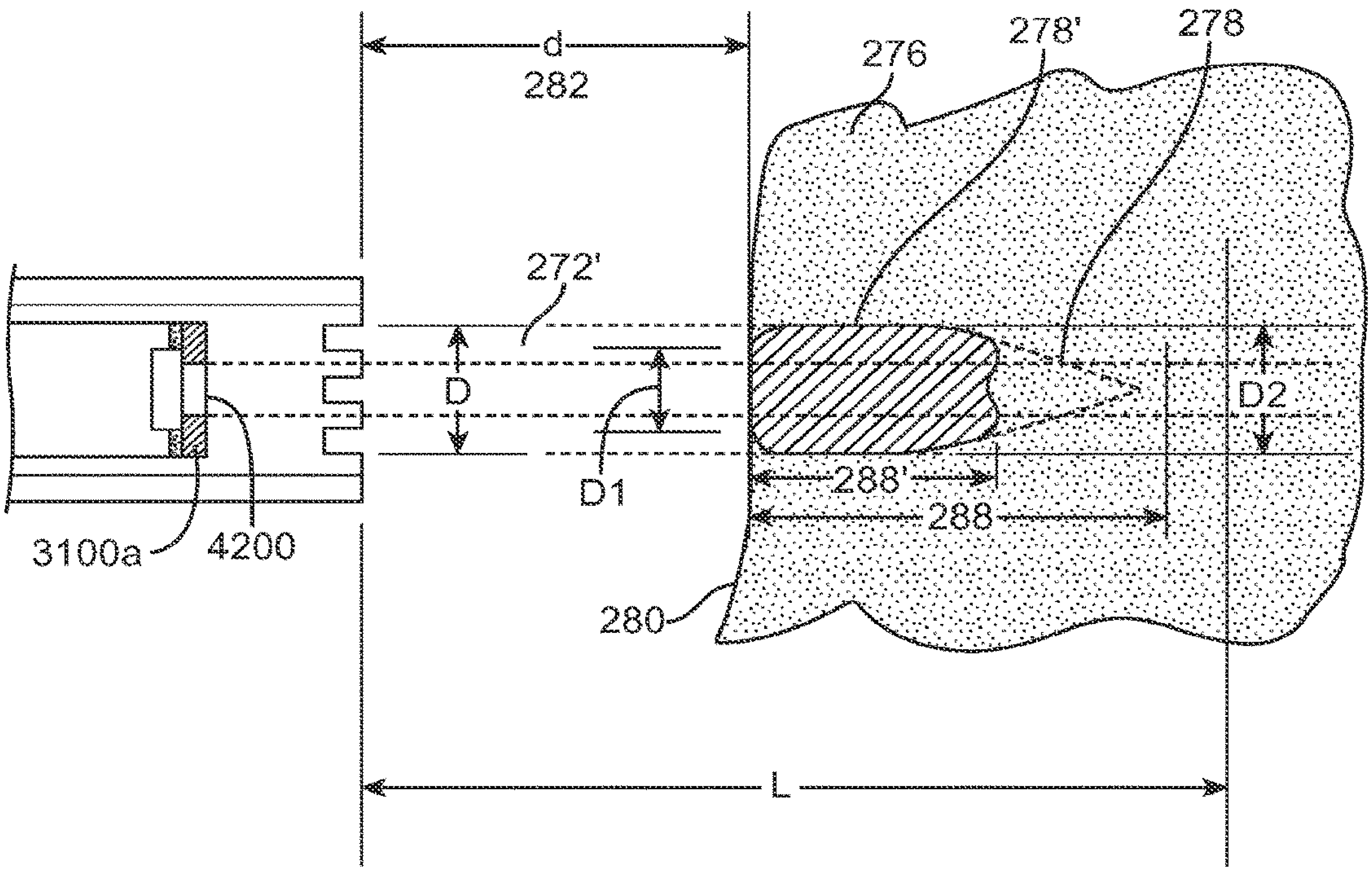

FIG. 8

METHODS FOR IMAGING AND ABLATING BODY TISSUE

CROSS-REFERENCE

The present application is a continuation of U.S. application Ser. No. 13/907,412 filed on May 31, 2013, which is a continuation of U.S. application Ser. No. 12/620,287 filed on Nov. 17, 2009, now U.S. Pat. No. 8,475,379, which is a non-provisional of, and claims the benefit of priority of U.S. Provisional Patent Application No. 61/115,403 filed Nov. 17, 2008, the entire contents of which are incorporated herein by reference.

The present application is related to U.S. Pat. No. 7,950,397 and U.S. Pat. No. 7,942,871 and copending U.S. patent application Ser. No. 12/480,929; Ser. No. 12/480,256; Ser. No. 12/483,174; Ser. No. 12/482,640; Ser. No. 12/505,326; Ser. No. 12/505,335; Ser. No. 12/609,759; Ser. No. 12/609,274; and Ser. No. 12/609,705. The present application is also related to U.S. Provisional Patent Application Nos. 61/148,809; and 61/254,997. The entire contents of each of the above referenced applications is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present application generally relates to systems and methods for creating ablation zones in human tissue. More specifically, the present application relates to transducer configurations used to create tissue lesions, and even more specifically to ultrasound transducers used to treat fibrillation of the heart. While the present application emphasizes treatment of atrial fibrillation, one of skill in the art will appreciate that this is not intended to be limiting, and that the systems and methods disclosed herein may also be used to treat other arrhythmias as well as to treating other conditions by creating lesions in tissue.

The condition of atrial fibrillation (AF) is characterized by the abnormal (usually very rapid) beating of the left atrium of the heart which is out of synch with the normal synchronous movement ('normal sinus rhythm') of the heart muscle. In normal sinus rhythm, the electrical impulses originate in the sino-atrial node ('SA node') which resides in the right atrium. The abnormal beating of the atrial heart muscle is known as 'fibrillation' and is caused by electrical impulses originating instead at points other than the SA node, for example, in the pulmonary veins (PV).

There are pharmacological treatments for this condition with varying degree of success. In addition, there are surgical interventions aimed at removing the aberrant electrical pathways from PV to the left atrium ('LA') such as the 'Cox-Maze III Procedure'. This procedure has been shown to be 99% effective but requires special surgical skills and is time consuming. Thus, there has been considerable effort to copy the Cox-Maze procedure using a less invasive percutaneous catheter-based approach. Less invasive treatments have been developed which involve use of some form of energy to ablate (or kill) the tissue surrounding the aberrant focal point where the abnormal signals originate in PV. The most common methodology is the use of radio-frequency ('RF') electrical energy to heat the muscle tissue and thereby ablate it. The aberrant electrical impulses are then prevented from traveling from PV to the atrium (achieving the 'conduction block') and thus avoiding the fibrillation of the atrial muscle. Other energy sources, such as microwave, laser, and

ultrasound have been utilized to achieve the conduction block. In addition, techniques such as cryoablation, administration of ethanol, and the like have also been used. Some of these methods and devices are described below.

There has been considerable effort in developing catheter based systems for the treatment of AF using radiofrequency (RF) energy. One such method includes a catheter having distal and proximal electrodes at the catheter tip. The catheter can be bent in a coil shape, and positioned inside a pulmonary vein. The tissue of the inner wall of the PV is ablated in an attempt to kill the source of the aberrant heart activity.

Another source used in ablation is microwave energy. One such intraoperative device consists of a probe with a malleable antenna which has the ability to ablate the atrial tissue.

Still another catheter based method utilizes the cryogenic technique where the tissue of the atrium is frozen below a temperature of −60 degrees C. This results in killing of the tissue in the vicinity of the PV thereby eliminating the pathway for the aberrant signals causing the AF. Cryo-based techniques have also been a part of the partial Maze procedures described above. More recently, Dr. Cox and his group have used cryoprobes (cryo-Maze) to duplicate the essentials of the Cox-Maze III procedure.

More recent approaches for the treatment of AF involve the use of ultrasound energy. The target tissue of the region surrounding the pulmonary vein is heated with ultrasound energy emitted by one or more ultrasound transducers. One such approach includes a catheter distal tip portion equipped with a balloon and containing an ultrasound element. The balloon serves as an anchoring means to secure the tip of the catheter in the pulmonary vein. The balloon portion of the catheter is positioned in the selected pulmonary vein and the balloon is inflated with a fluid which is transparent to ultrasound energy. The transducer emits the ultrasound energy which travels to the target tissue in or near the pulmonary vein and ablates it. The intended therapy is to destroy the electrical conduction path around a pulmonary vein and thereby restore the normal sinus rhythm. The therapy involves the creation of a multiplicity of lesions around individual pulmonary veins as required.

Yet another catheter device using ultrasound energy includes a catheter having a tip with an array of ultrasound elements in a grid pattern for the purpose of creating a three dimensional image of the target tissue. An ablating ultrasound transducer is provided which is in the shape of a ring which encircles the imaging grid. The ablating transducer emits a ring of ultrasound energy at 10 MHz frequency.

While such ablation therapies alone are promising, it is preferred that devices and systems combine these ablation therapies with imaging capabilities in a single unit. It would be particularly useful to provide sensing or imaging (often used interchangeably) of the treatment region to properly position the ablation device relative to the treatment region, as well as to evaluate progression of the treatment. Such imaging assists the system or the operator to ensure that only the targeted tissue region is ablated. Furthermore, in a moving target such as heart tissue, the original target identified by imaging, can move and thus non-target tissue may be inadvertently ablated. Hence, contemporaneous (or almost contemporaneous) imaging and ablation minimizes the risk of ablating non-target tissue. Thus, one unmet need using ultrasound techniques for tissue ablation is to provide a device capable of both imaging as well as ablation.

Attaining this goal involves redesigning the key components of a conventional ultrasound ablation system to also provide an imaging function. Typically, ultrasound ablation is accomplished using a transducer assembly. The transducer assembly comprises a transducer element, commonly one or more piezoelectrically active elements such as lead zirconate titanate (PZT) crystals. The PZT crystals often include an acoustical (impedance) matching layer on the ablating face to facilitate efficient power transmission and to improve the imaging performance. Further, the crystals may be bonded to a backing on the non-ablative face to reflect or absorb any ultrasound beams in the appropriate direction. The conventional acoustic transducers which are typically employed for the therapeutic purposes are acoustically large, often single-crystal devices having a narrower bandwidth in the frequency domain than is required for good imaging performance. Although they are designed to efficiently transmit acoustic energy to the target tissue, crystal devices with narrow bandwidth have previously been viewed as unsuited for imaging. This has been due to the perceived inability of conventional ablation transducers to handle the bandwidth of the ultrasound frequencies that would be optimized for both imaging and ablation. While ablation can be achieved using a narrower range of frequencies, imaging is usually performed using a wide range of frequencies. Thus, it is desirable that the PZT be able to accommodate a wider bandwidth than used for ablation in order to accommodate the imaging bandwidth.

Wider transducer bandwidths are often achieved through the use of matching layers. Matching layers typically use materials with acoustic impedance between the acoustic impedances of the PZT and the tissue, and with a thickness approaching ¼ wavelength of the ultrasound frequency utilized. While matching layers are often used to improve the transmission of ultrasound from the PZT into the tissue, they also can be used to dampen the mechanical response of the PZT and broaden its bandwidth. This dampening can result in some reduction of transducer efficiency. Furthermore wide bandwidth transducers may be unable operate at high power levels because they cannot be cooled effectively, partly due to the thermally insulating properties of the matching layer. A conventional PZT transducer with a higher bandwidth may often be only 30%-50% efficient in converting the electrical energy to acoustic energy, and much of the energy is converted to heat and lost in the transducer assembly. In addition to the lack of efficiency in converting to ultrasound energy, the heat further reduces the PZT efficiency and may cause the PZT crystal to depole and stop functioning as a transducer.

Thus, an additional challenge is to cool the transducer to maintain a lower operating temperature than is presently provided for in commercially available systems. A cooled transducer can be driven harder, i.e., it can tolerate higher electric powers and produce higher acoustic powers. This higher acoustic output is useful in increasing the lesion size and/or reducing the amount of time required to create a lesion. Both of these attributes are important in the clinical application of treating AF.

One method of cooling the transducer is to take advantage of the power density and heat dissipation that are dependent on the size of the transducer. As the diameter (and corresponding surface area) of the transducer increases, the power density drops, and the heat dissipation per unit surface area also drops. If large enough, conventional cooling methods may suffice to keep the transducer cool. However, in a catheter suitable for ablation using an interventional approach, the transducer must necessarily be small and yet also be able to generate the power density levels required to ablate tissue. In such a transducer, size is not a suitable method of regulating the transducer's temperature. Thus, due to the small transducer size and consequent high power densities and low heat dissipation, alternative approaches are warranted for cooling the transducer.

One potential solution is the use of fluids to cool the transducer. Commonly, bodily fluids, such as blood flowing around the transducer, are used as a cooling fluid. However, blood tends to denature and collect around the transducer when heated. In addition to the attendant problems of possibly creating a clot in the atrium, the denatured blood may also adhere to the face of the transducer and create a layer of insulation, thereby further decreasing the performance of the transducer. In contrast, introduced (non-bodily) fluids such as saline or water do not have the same attendant problems as blood and are useful in maintaining lower transducer operating temperatures. However, in order to be effective, these introduced fluids have to be effectively transported to the entire transducer to cool all the faces of the transducer. If fluid transport is inadequate, the uncooled regions may develop "hot spots" that can impede the efficiency of the transducer.

While some devices, such as single crystal ultrasound therapy systems have been reported for both imaging and therapeutic purposes, none disclose a method for cooling the entire transducer. Other multi-crystal transducer assemblies are also available that circumvent the concerns of the single-crystal model. Some of these systems provide a method for cooling the back of the transducer crystals. However, none of these systems or methods include cooling of the entire transducer crystal. As mentioned above, it is important to cool all the faces of the transducer (front and the back). Cooling only part of the transducer may lead to "hot spots" on some areas of the transducer, thereby decreasing the efficiency of the transducer in a situation where both ablation and imaging are necessary.

To realize combined imaging and ablation capabilities, some systems have separate imaging and ablation units. For example one commercially available system includes a treatment and imaging system. This system comprises a probe with an ultrasound transducer adapted to obtain imaging information from a patient treatment region, and also a separate arm member to deliver ultrasonic energy to the treatment region. Naturally, these are bulky and not well suited for use in catheter based systems. A variant of the combined imaging and ablation units is using separate transducer elements for imaging and ablation. This approach suffers from many shortcomings including functionally, the ablated tissue is not identical to the imaged tissue, and structurally this configuration of discrete imaging and ablating elements occupies more space in a housing, where space is limited in a transducer assembly, especially when the transducer is at the tip of the catheter as used in an interventional approach. Additionally, a multi-element device is more expensive and inconvenient to manufacture, along with the complicated arrangements necessary for cooling the transducer elements. Further, multi-element devices are prone to misalignment, which may make them more difficult to use. Also, multi-element devices typically require more complex and expensive systems for their control and use.

Thus, additional improvements are still desired in the field of ultrasound devices with combined imaging and ablating capabilities. In particular, it would be desirable to provide a device with a single-crystal transducer assembly where all faces of the transducer crystal are cooled to protect and preserve the operating efficiency. It would also be desirable to provide such a system that is easy to use, easy to manufacture and that is lower in cost than current commercial systems.

2. Description of Background Art

Patents related to the treatment of atrial fibrillation include, but are not limited to the following: U.S. Pat. Nos. 7,393,325; 7,142,905; 6,997,925; 6,996,908; 6,966,908; 6,964,660; 6,955,173; 6,954,977; 6,953,460; 6,949,097; 6,929,639; 6,872,205; 6,814,733; 6,780,183; 6,666,858; 6,652,515; 6,635,054; 6,605,084; 6,547,788; 6,514,249; 6,502,576; 6,500,121; 6,416,511; 6,383,151; 6,305,378; 6,254,599; 6,245,064; 6,164,283; 6,161,543; 6,117,101; 6,064,902; 6,052,576; 6,024,740; 6,012,457; 5,629,906; 5,405,346; 5,314,466; 5,295,484; 5,246,438; 4,757,820 and 4,641,649.

Patent Publications related to the treatment of atrial fibrillation include, but are not limited to International PCT Publication Nos. WO 2005/117734; WO 1999/002096; and U.S. Patent Publication Nos. 2005/0267453; 2003/0050631; 2003/0050630; and 2002/0087151.

Scientific publications related to the treatment of atrial fibrillation include, but are not limited to: Haissaguerre, M. et al., *Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins*, New England J Med., Vol. 339:659-666; J. L. Cox et al., *The Development of the Maze Procedure for the Treatment of Atrial Fibrillation*, Seminars in Thoracic & Cardiovascular Surgery, 2000; 12: 2-14; J. L. Cox et al., *Electrophysiologic Basis, Surgical Development, and Clinical Results of the Maze Procedure for Atrial Flutter and Atrial Fibrillation*, Advances in Cardiac Surgery, 1995; 6: 1-67; J. L. Cox et al., *Modification of the Maze Procedure for Atrial Flutter and Atrial Fibrillation. II, Surgical Technique of the Maze III Procedure*, Journal of Thoracic & Cardiovascular Surgery, 1995; 110: 485-95; J. L. Cox, N. Ad, T. Palazzo, et al. *Current Status of the Maze Procedure for the Treatment of Atrial Fibrillation*, Seminars in Thoracic & Cardiovascular Surgery, 2000; 12: 15-19; M. Levinson, *Endocardial Microwave Ablation: A New Surgical Approach for Atrial Fibrillation*; The Heart Surgery Forum, 2006; Maessen et al., *Beating Heart Surgical Treatment of Atrial Fibrillation with Microwave Ablation*, Ann Thorac Surg 74: 1160-8, 2002; A. M. Gillinov, E. H. Blackstone and P. M. McCarthy, *Atrial Fibrillation: Current Surgical Options and their Assessment*, Annals of Thoracic Surgery 2002; 74:2210-7; Sueda T., Nagata H., Orihashi K., et al., *Efficacy of a Simple Left Atrial Procedure for Chronic Atrial Fibrillation in Mitral Valve Operations*, Ann Thorac Surg 1997; 63:1070-1075; Sueda T., Nagata H., Shikata H., et al.; *Simple Left Atrial Procedure for Chronic Atrial Fibrillation Associated with Mitral Valve Disease*, Ann Thorac Surg 1996; 62:1796-1800; Nathan H., Eliakim M., *The Junction Between the Left Atrium and the Pulmonary Veins, An Anatomic Study of Human Hearts*, Circulation 1966; 34:412-422; Cox J. L., Schuessler R. B., Boineau J. P., *The Development of the Maze Procedure for the Treatment of Atrial Fibrillation*, Semin Thorac Cardiovasc Surg 2000; 12:2-14; and Gentry et al., *Integrated Catheter for 3-D Intracardiac Echocardiography and Ultrasound Ablation*, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 51, No. 7, pp 799-807.

SUMMARY OF THE INVENTION

The present invention discloses a transducer assembly with combined imaging and therapeutic capabilities that may be used to create lesions in tissue. In preferred embodiments, the transducer assembly is used to ablate tissue to create a conduction block in the target tissue which blocks aberrant electrical pathways. Thus, the transducer assembly may be used as a treatment for fibrillation or other arrhythmias, as well as other conditions requiring creation of a lesion in tissue.

In a first aspect of the present invention, a transducer system comprises a transducer element comprising a proximal surface and a distal surface, and a first heat sink attached to the distal surface of the transducer element. The system also has a second heat sink attached to the proximal surface of the transducer element, and a base coupled to the first and second heat sinks The base is configured to allow fluid flow past the transducer element for cooling of the and distal surfaces of the transducer element, and the heat sinks

The system may further comprise a tubular jacket configured to house the base, the transducer element, and the first and second heat sinks The tubular jacket may comprise at least one fluid exit port configured to allow fluid to exit the tubular jacket. The first heat sink may comprise a first bonding portion and a first substantially bent portion. The first bonding portion may be bonded to the distal surface of the transducer, and the first substantially bent portion may protrude proximally from the transducer element, thereby conducting heat away from the distal surface of the transducer element. The first bonding portion may comprise a material whose composition and dimension provides an acoustically matching layer on the distal surface of the transducer element. The first bonding portion may comprise a material chosen from the group consisting of aluminum, graphite, metal-filled graphite, ceramic, an amalgam of graphite and copper or tungsten, and an epoxy-filled metal. The bonding portion may be in electrical and/or thermal communication with the distal surface of the transducer element. Electrical communication between the bonding portion and the distal surface may be established by direct contact between the bonding portion and the distal surface. The direct contact may be controlled by surface roughness of the bonding portion and the distal surface.

The second heat sink may comprise a second bonding portion and a second substantially bent portion. The second bonding portion may be bonded to the proximal surface of the transducer, and the second substantially bent portion may protrude proximally from the transducer element, thereby conducting heat away from the proximal surface of the transducer element. The second bonding portion may comprise a material whose composition is acoustically mismatched to an acoustic impedance of the transducer element, thereby providing a reflective backing layer on the proximal surface of the transducer element. The second bonding portion may comprise a metal such as copper. An air pocket may be disposed between the proximal surface of the transducer and the second heat sink.

The transducer element may comprise a substantially flat circular disc, and the transducer element may operate at a first power level in a first frequency range and a second power level in a second frequency range. The first frequency range may be used for ultrasonically imaging tissue and the second frequency range may be used for creating tissue lesions. The first frequency range may be 5 MHz to 30 MHz and the second frequency range may be 10 to 18 MHz.

The first and second bonding portions may comprise a matrix containing perforations such that the first bonding portion is acoustically matched and the second bonding portion is acoustically mismatched to the acoustic impedance of the transducer element. The system may further comprise an elongate flexible shaft having a proximal end and a distal end, and the transducer may be disposed adjacent the distal end of the shaft. The system may also comprise a cooling fluid in fluid communication with the transducer. The system may comprise a temperature sensor adjacent the transducer for monitoring temperature of the transducer or cooling fluid flowing therepast. Adjustments to the cooling fluid flow rate or the transducer power levels may be made based on the monitored temperature.

In another aspect of the present invention, a method of ablating tissue comprises introducing an ablation device into a patient. The device comprises an ultrasound transducer element configured to operate at a first power level and at a second power level. The first power level is used for ultrasonically imaging tissue and identifying a target tissue, and the second power level is used for ablating the target tissue. Operating the transducer element at the first power level allows imaging of a portion of the tissue and identification of the target tissue. Operating at the second power level ablates the target tissue. The ultrasound transducer surfaces are cooled during operation.

The transducer element may comprise a proximal surface and a distal surface, and the device may further comprise first and second heat sinks bonded to the distal and proximal surfaces of the transducer element, respectively. The cooling step may comprise introducing fluid to the transducer element and to the first and second heat sinks during operation of the transducer element, thereby further cooling the transducer element. The transducer element may comprise first and second portions. The first portion may be configured to operate at the first power level and the second portion may be configured to operate at the second power level. The first portion may be operated at the first power level concurrently with operation of the second portion at the second power level. The introducing step may comprise passing the ablation device transseptally across a septal wall of the patient's heart. The introducing step may also comprise positioning the ablation device into a left atrium of the patient's heart. There may not be direct contact between the transducer and the target tissue.

These and other embodiments are described in further detail in the following description related to the appended drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A illustrates an exemplary system for treating tissue using a transducer assembly.

FIGS. **1**B-**1**C illustrate exemplary embodiments of a transducer assembly.

FIGS. **2**A-**2**D illustrate alternative embodiments of the transducer element.

FIG. **3** illustrates the transducer element with a first heat sink.

FIG. **4** illustrates the transducer element with a second heat sink.

FIG. **5** illustrates the transducer assembly in a tubular jacket.

FIG. **6** illustrates an ablation pattern in tissue.

FIGS. **7**A-**7**D illustrate the progression of ablation in tissue.

FIG. **8** illustrates an alternative lesion shape.

DETAILED DESCRIPTION OF THE INVENTION

Although the detailed description contains many specifics, these should not be construed as limiting the scope of the invention but merely as illustrating different examples and aspects of the invention. It should be appreciated that the scope of the invention includes other embodiments not discussed in detail above. Various other modifications, changes and variations which will be apparent to those skilled in the art may be made in the arrangement, operation and details of the method and apparatus of the present invention disclosed herein without departing from the spirit and scope of the invention as described here.

The present invention relates to creating ablation zones in human tissue, and more specifically to transducer assemblies (or subassemblies) that are used for creating tissue lesions. FIG. **1**A is a diagrammatic illustration of an exemplary embodiment of a system for creating ablation zones in human tissue, as described in the above referenced related parent applications. A catheter device C is housed within a sheath S. A proximal portion of the catheter C is coupled to a console P. A distal portion of the catheter C, comprising an ultrasonic transducer subassembly T, is introduced into the heart, preferably transseptally, into the left atrium (LA), adjacent the pulmonary veins PV of a patient. The transducer subassembly T is energized to provide ultrasonic energy for ablating tissue. The console P controls energy delivery to the transducer subassembly T, as well as movements of the distal portion of the catheter C to trace ablation paths. Additional details on the ablation system are disclosed in U.S. Provisional Patent Application No. 61/254,997 previously incorporated herein by reference.

For brevity, the transducer subassemblies are described herein with respect to one embodiment of a catheter for sensing and ablating tissue. However, the transducer assemblies of this invention may be utilized with any suitable device in both medical and non-medical fields.

The transducer subassemblies comprise transducer elements and are configured such that the same transducer element may be used to both image (for example, in A-mode) and ablate. The transducer elements may be in the shape of a disc, or other shapes may be used for the transducer elements. The transducer subassemblies are also configured for effective cooling of the transducer elements, in order to increase the efficiency of transduction. This is accomplished by affixing (e.g. by bonding, welding, snap fitting, etc.) a distal and a proximal heat sink to the transducer element, thereby conducting heat away from the transducer element. In order to further increase efficiency, the distal heat sink comprises an acoustically matching layer and the proximal heat sink comprises an acoustically mismatched backing layer. Additionally, each of the heat sinks is configured to allow for a cooling substance (e.g., a fluid such as saline, water) to be directed to and dissipate the heat from the proximal and distal surfaces (hereinafter also referred to as "faces") of the transducer element.

As shown in FIG. **1**B, a transducer subassembly **3000** is placed at or near the distal portion of a catheter **2000** and contained within a tubular jacket **3400**. The catheter **2000** may be any suitable catheter and comprises at least one lumen **2100**. The components of transducer subassembly **3000** are shown in an assembled view in FIG. **1**B, and in an exploded view in FIG. **1**C. The transducer subassembly **3000** comprises a transducer element **3100** having a distal face **3102** and a proximal face **3104**. The transducer subassembly **3000** further comprises heat sinks that serve to cool the transducer element **3000** by conducting heat away from it. Specifically, the transducer subassembly **3000** comprises a distal heat sink **3300** bonded to the distal face **3102** of the transducer element **3100**, and a proximal heat sink **3200** bonded to the proximal face **3104** of the transducer element **3100**.

The heat sinks are further configured to increase the operating efficiency of the transducer element **3000** through acoustic matching and acoustic reflection. Specifically, and as described in further detail below, the distal heat sink **3300** comprises an acoustically matching layer portion, i.e., a portion whose composition and thickness provides a ¼ wavelength matching layer between the transducer element **3100** and any fluid in front of the transducer subassembly **3000**. The proximal heat sink **3200** comprises an acoustically mismatched layer portion, i.e., a portion whose composition is acoustically mismatched to the acoustic impedance of the transducer element **3100**, thereby reflecting ultrasound waves emanating from the transducer element **3100** back towards the transducer element **3100**. These portions are more fully described below.

The transducer subassembly **3000** also comprises a base **3500** anchoring the heat sinks **3200** and **3300**, with the transducer element **3100** bonded between the heat sinks The transducer subassembly **3000** is powered using one or more electrical cables **3600** bonded to each of the heat sinks **3200** and **3300**. These electrical cables **3600** are exemplarily provided through a pair of twisted wires, as shown in FIGS. **1**B and **1**C. As will be appreciated, they could also be coaxial or separate untwisted wires. The heat sinks **3200** and **3300** comprise electrical attachments (not shown) for electrically coupling the heat sinks **3200** and **3300** to the electrical cables **3600**, thereby providing electrical power to the transducer element **3100**. The transducer element **3100** comprises electrode platings on the distal and proximal faces in order to distribute the electrical energy over the faces of the transducer element **3100**.

As disclosed herein, the transducer element **3100** comprises a single transducer element. However, those skilled in the art would appreciate that this single element may be comprised of smaller sub-elements. The transducer is of a suitable size to fit into a catheter configured to be introduced percutaneously into the atria of the heart. For example, in one embodiment, the transducer diameter is less than 0.2 inches, and preferably less than 0.15 inches.

Further, the transducer element may comprise a variety of geometries, as well as a variety of acoustically active and inactive portions. Such transducer element properties in turn influence the transducer's imaging and ablative properties, such as the shape of the created ablation lesions. These concepts of using transducer elements of various shapes and sizes (sub-elements) are further described below.

For example, in the embodiment shown in FIGS. **1**B and **1**C, the transducer element **3100** is a flat, circular disc that transmits ultrasound energy from its proximal and distal faces. The transducer element **3100** may alternatively have more complex geometry, such as either concave or convex, to achieve an effect of a lens or to assist in apodization (i.e., in selectively decreasing the vibration of a portion or portions of the surfaces of the transducer element **3100**) and management of the propagation of the ultrasound beam.

Other exemplary transducers are shown in FIGS. **2**A through **2**D. For example, as shown in FIGS. **2**A and **2**B, the transducers **3100***a* and **3100***b* include at least one acoustically inactive portion **4200**, with the remainder of the transducer surface comprising an acoustically active portion. In these embodiments, the acoustically inactive portion **4200** does not emit an energy beam when the transducer is energized, or may alternatively emit an energy beam with a very low (substantially zero) energy. The acoustically inactive portion **4200** has several functions. For instance, the shape of a lesion produced by ablating tissue using such a transducer may correspond with the shape of the acoustically active ablating portions. For example, in the circular embodiment shown in FIGS. **1**B and **1**C, the shape of the lesion will be tear-drop shaped. However, in the annular embodiment shown in FIG. **2**A, the shape of the lesion will be approximately tooth-shaped or a blunted tear-shaped. This is because the acoustically inactive portion **4200** in FIG. **2**A will preclude prolonged ablation at the corresponding central portion of the tissue. Since prolonged ablation of tissue creates a deeper ablation, the presence of acoustically inactive portion **4200** precludes ablation from reaching further into the tissue at the central portion. The lesion thus is approximately tooth-shaped or blunted tear-shaped, as illustrated by the exemplary lesion shape L of FIG. **2**A, rather than tear-shaped.

In addition to influencing the shape of the created ablation lesion, acoustically inactive portion **4200**, in any of the embodiments shown, further functions to aid in the temperature regulation of the transducer elements **3100***a* and **3100***b*, i.e., in preventing the transducer elements from becoming too hot.

Acoustically inactive portions may be created in a variety of ways. In one embodiment, an acoustically inactive portion **4200** is a hole or gap defined by the boundary of the acoustically active region of the transducer element. In such an embodiment, an optional coolant source may be coupled to (or in the case of a coolant fluid, it may flow through) the hole or gap defined by the transducer element to further cool and regulate the temperature of the transducer element.

In another embodiment, the acoustically inactive portion **4200** may comprise a material composition with different properties from that of the active region of the transducer element. For example, the acoustically inactive material may be made of a metal, such as copper, which further functions to draw or conduct heat away from the transducer element. Alternatively, the acoustically inactive portion **4200** may be made from the same material as the transducer element, but with the electrode plating removed or disconnected from the electrical attachments. The acoustically inactive portion **4200** may be disposed along the full thickness of the transducer element, or may alternatively be a layer of material on or within the transducer element that has a thickness less than the full thickness of the transducer element.

For example, as shown in FIG. **2**A, the transducer element **3100***a* is a doughnut-shaped transducer that comprises a hole (or acoustically inactive portion) **4200** in the center portion of the otherwise circular disc-shaped transducer element. The transducer element **3100***a* of this embodiment has a circular geometry, but may alternatively be elliptical, polygonal as shown in FIG. **2**B, or any other suitable shape. The transducer element **3100***a* includes a singular, circular acoustically inactive portion **4200**, but may alternatively include any suitable number of acoustically inactive portions **4200** of any suitable geometry, as shown in FIG. **2**B. Exemplary geometries of acoustically inactive portions include circular, square, rectangular, elliptical, polygon, or any other shaped region. The total energy emitted from the transducer element is related to the acoustically active surface area of the transducer element. Therefore, the size and location of acoustically inactive portion(s) **4200** may sufficiently reduce the heat build-up in the transducer element, while allowing the transducer element to provide as much output energy as possible or as desired.

As disclosed herein, the transducer elements may optionally be configured to operate at more than one frequency. This allows them to be used for multi-frequency ablating or for contemporaneous ablation and diagnosis. For example, such a multi-frequency transducer element may be operated intermittently at a first power level using a first frequency range that is used to image a portion of the tissue in order to identify a target tissue, and operated at a second power level using a second frequency range that is used to ablate the target tissue. In one embodiment, the imaging frequency is in the range of about 5 MHz to 30 MHz, and the ablation frequency is preferably in the range of 5 to 25 MHz, more preferably in the range 8 to 20 MHz, and even more preferably in the range 10 to 18 MHz. The transducers achieving these configurations are shown to exemplarily be annular transducers or grid arrays.

As shown in FIGS. **2**C and **2**D, the transducer elements **3100***c* and **3100***d* are configured to be capable of transmitting at more than one frequency. Specifically, as shown in FIG. **2**C, the transducer element **3100***c* includes a plurality of annular transducer portions **4400**. The plurality of annular transducer portions is a plurality of concentric rings, but may alternatively have any suitable configuration with any suitable geometry, such as elliptical or polygonal. Optionally, the transducer element **3100***c* includes one or more acoustically inactive portions **4200**, such as the center portion of the transducer **3100***c*. The plurality of annular transducer portions **4400** includes at least a first annular portion and a second annular portion. The first annular portion may have material properties that differ from those of the second annular portion, such that the first annular portion emits a first energy beam that is different from a second energy beam emitted by the second annular portion. Furthermore, the first annular portion may be energized with a different frequency, voltage, duty cycle, power, and/or for a different length of time from the second annular portion. Alternatively the first annular portion may be operated in a different mode from the second annular portion. For example, the first annular portion may be operated in a therapy mode, such as ablation mode, which delivers a pulse of ultrasound energy sufficient for heating the tissue. The second annular portion may be operated in an imaging mode, such as A-mode, which delivers a pulse of ultrasound of short duration, which is generally not sufficient for heating of the tissue but functions to detect characteristics of the target tissue and/or environment in and around the ultrasound delivery system. The first annular portion may further include a separate electrical attachment from that of the second annular portion.

In a another embodiment of a multi-frequency transducer element shown in FIG. **2**D, the transducer element **3100***d* includes a grid of transducer portions **4600**. The grid of transducer portions **4600** has any suitable geometry such as circular, rectangular, elliptical, polygonal, or any other suitable geometry. The transducer element **3100***d* in this variation may further include one or more transducer portions that are acoustically inactive. The grid of transducer portions **4600** includes at least a first transducer portion and a second transducer portion. The first transducer portion and the second transducer portion are portions of a single transducer with a single set of material properties. The first transducer portion is energized with a different frequency, voltage, duty cycle, power, and/or for a different length of time from the second transducer portion. Furthermore, the first transducer portion may be operated in a different mode from the second transducer portion. For example, similar to the description above, the first transducer portion may operate in a therapy mode, such as ablate mode, while the second transducer portion may operate in a imaging mode, such as A-mode. The first transducer portion may further include a separate electrical attachment from that of the second transducer portion. For example, the first transducer portion may be located towards the center of the transducer element **3100***d* and the second transducer portion may be located towards the outer portion of the transducer element **3100***d*. Further, the second transducer portion may be energized while the first transducer portion remains inactive. In other embodiments, the first transducer portion has material properties that differ from those of the second transducer portion, such that the first transducer portion emits a first energy beam that is different from a second energy beam emitted from the second transducer portion. In such an embodiment, the first transducer portion may also be energized with a different frequency, voltage, duty cycle, power, and/or for a different length of time from the second transducer portion.

Turning now to the heat sinks **3200** and **3300**, FIG. **3** shows the proximal heat sink **3200**. In this embodiment, the proximal heat sink **3200** comprises a bonding portion **3210** and a substantially bent portion forming legs **3220** that are generally orthogonal to the bonding portion **3210**. The proximal heat sink further comprises at least one electrical attachment **3230**. Similarly, the distal heat sink comprises an electrical attachment **3330** (shown in FIG. **4**). The electrical wires **3600** are connected to the electrical attachments **3230** and **3330**. Unlike conventional electrical attachments to a transducer crystal, where the electrical leads are connected to the opposing faces of the crystal, the disclosed arrangement eliminates "hot spots" and results in a uniform electrical power density across the surface of the crystal. Additionally, this results in an easier assembly or manufacturing process.

The bonding portion **3210** is bonded to the proximal face of the transducer element **3100** with a suitable bonding material such as an epoxy to form a bond layer. Though shown as substantially flat in this embodiment, one skilled in the art will appreciate that the bonding portion **3210** may be any suitable configuration such as a concave portion to still maintain the functionality described herein. The substantially bent portion **3220** comprises legs, or elements that protrude proximally from the transducer element **3100**. Further, the bent portion **3220** is configured in a manner to allow for fluid to flow through the bent portion and also allows the fluid to surround and cool the proximal face of the transducer element **3100**. The fluid that could be accommodated within the bent portion could be any suitable fluid that achieves an appropriate balance between having an effective heat sink and minimizing acoustic reverberations that degrade image performance. The proximal heat sink **3200** is formed from a suitable material such as copper of a suitable thickness. The thickness of the material for this heat sink preferably ranges between 0.0001 inches to 0.01 inches for a copper heat sink.

Proximal heat sink **3200** serves to cool the proximal face of the transducer by conducting and dissipating the heat away from the transducer element **3100**. Heat from the transducer element **3100** is absorbed by the bonding portion **3210**, and conducted to the bent portion **3220** where it is dissipated into the circulating fluid. This dissipation provides some cooling to the proximal face of the transducer element **3100**. Additionally, the bent portion **3220** is configured in a manner to allow for fluid to surround and cool the proximal face of the transducer element **3100**. For example, as shown in FIG. **3**, the bent portion **3220** provides for one or more pockets behind the transducer element **3100** where a fluid may be introduced to flow and cool both the transducer element **3100** as well as the proximal heat sink **3200** that has dissipated heat from the proximal face of the transducer element **3100**.

As described above, in addition to dissipating the heat, the proximal heat sink **3200** also serves as a heat spreader to reduce hot spots in the transducer element **3100**, and thereby preserve it over its entire face. Without this heat spreading, the center of the transducer element **3100** would be substantially hotter than the rest of the transducer element **3100**.

The bonding portion **3210** can be configured to maximize the amount of reflected energy transmitted from the transducer element **3100**. Since many metals suitable for heat sink applications have acoustic impedances that are not too dissimilar from PZT, the boundary between PZT and the heat sink itself does not provide a very effective reflective interface. However, another material immediately proximal to the heat shield could be selected so that it provides an efficient acoustic reflector. For example, air provides an excellent acoustic mismatch, as does water, and therefore acts as good reflectors. Water is preferred since it also acts as a thermal conductor, even though it is not quite as effective a reflector as air. Air could be used, provided that it does not interfere with the flow of cooling fluid around the transducer assembly. To accomplish this, the bonding portion of **3210** could be constructed from two metal layers capturing a third thin layer of air in between. Alternatively, a backing material may be located proximal to the proximal heat sink **3200** to provide an acoustically absorptive medium to minimize reverberations to further optimize imaging performance. Such backing materials may optionally be made of combinations of epoxy, metal particles, tungsten and the like.

Additionally or alternatively, the transducer element **3100** or the transducer subassembly **3000** may be placed on a tripod-style structure (not shown) such that the proximal surface of the transducer element **3100** faces into the tripod. In this configuration, a pocket forms in the space between the transducer element **3100** and the tripod base. This pocket serves as an alternative backing with the same two-fold purpose. First, it is acoustically mismatched and thereby reflective of the ultrasound waves emanating from the transducer element **3100**. Second, as fluid (for example saline or water) is introduced into the transducer assembly **3000**, the pocket also allows for the fluid to come into contact with the transducer element **3100** and thereby provide for additional cooling.

Alternatively, another suitable acoustically mismatched material with reasonable thermal conduction could be used in place of fluid. Such materials include metal with trapped air, for example steel wool or porous metal with entrapped air. For example, the rear of the PZT may comprise a thin heat spreader comprising the entire rear face with a pocket of porous metal attached behind. As another example, the center of the PZT could be further cooled by providing a thermally conducting center post as part of the heat sink, allowing an annular ring of air to be trapped behind the bonding portion **3210**.

As mentioned above, additional cooling can be provided by a distal heat sink **3300** (which also serves as a heat spreader) for distributing the heat and cooling the distal face of the transducer element **3100**. As shown in FIG. **4**, the distal heat sink **3300** also comprises a bonding portion **3310** and a substantially bent portion **3320** that is orthogonal to the flat portion **3310**. The distal heat sink further comprises at least one electrical attachment **3330**. The distal heat sink **3300** is configured such that the bonding portion **3310** is bonded to the distal face of the transducer element **3100**. The substantially bent portion **3320** comprises elements or legs that protrude proximally from the transducer element **3100**. Thus the bent portion **3320** of the distal heat sink **3300** is adjacent to the bent portion **3220** of the proximal heat sink **3200**. As mentioned above, the bonding portion **3310** is further configured to serve as an acoustically matching layer for the transducer element **3100**. To provide an acoustically matching composition that is also thermally conductive, the bonding portion **3310** is made of a suitable material such as aluminum; other such suitable materials include graphite, metal-filled graphite or ceramic, or an amalgam of graphite and copper or tungsten, in suitable thickness that range from 0.026 inches to 0.00026 inches so that it is ¼ wavelength at the desired frequency. The bonding portion **3310** is bonded to the distal face of the transducer element **3100** with a suitable bonding material such as an epoxy to form a bond layer.

Additionally and optionally, the bonding portion **3310** comprises perforations or holes **3315** that may be filled with epoxy applied in a layer of a suitable thinness to enhance the acoustic impedance matching. Perforations in the distal matching layer can be accomplished in many ways. The perforated structure is made of a combination of metal matrix containing open spaces, later to be filled with an epoxy material. For example, the metal matrix can be a wire grid. Alternatively, the perforated structure may be a matrix of epoxy film, and the holes may be filled with a metal such as aluminum. Additionally, the ratio of epoxy to the metal mixture is configured to enhance acoustic impedance matching. The acoustic impedance is determined by the acoustic impedance of the two composite materials, and the ratio of the mixture. For example, using aluminum and EPO-TEK® 377 (Epoxy Technology, Inc., Billerica, Mass.) the appropriate ratio is 35-60% volume fraction of epoxy and a good acoustic impedance matching is achieved at a 40-50% volume fraction of epoxy and an ideal match about 41%. Additionally, the perforations or holes **3315** have a sufficiently small diameter as compared to the wavelength of the ultrasonic beam, thereby allowing the bonding portion **3310** to appear homogeneous to the propagating waves emanating from the transducer element **3100**.

Similar to the construction of using bonding portion **3310** with perforations or holes to achieve acoustic impedance matching, the bonding portion **3210** at proximal surface of the transducer crystal also may benefit from using perforations or holes in the material used to achieve acoustic impedance mismatch. Such materials may include copper, tungsten and the like. Alternatively, an epoxy layer with metal particles sprinkled in it and a distribution of holes or perforations may achieve the same purpose of providing acoustic impedance mismatch.

Both non-conductive and conductive epoxy (with metal particles such as silver) could be used to form either the proximal or distal bond layer. In one embodiment, the epoxy is exemplarily a non-conductive epoxy of a low viscosity (e.g., EPO-TEK® 377). The epoxy is applied in a layer of suitable thinness to minimize its impact on acoustic impedance matching, while maximizing thermal conduction to cool the transducer **3100**. Additionally, the bond layers are also configured to electrically connect the heat sinks **3310** and **3210** to the transducer **3100**. This is successfully accomplished without the use of conductive epoxy by configuring the transducer **3100** faces and the bonding portions **3310** and **3210** to be rough. Thereafter, the distal and the proximal faces of the transducer element **3100** are bonded to their relevant heat sinks with electrically non-conductive epoxy. Each bond layer is of sufficient thinness to allow the surface roughness of the transducer **3100** to electrically contact the surface roughness of the heat sinks **3310** and **3210**. This allows the rough surfaces of the transducer element **3100** to come into direct electrical contact with their relevant heat sinks, thereby obviating the need for using electrically conductive epoxy (which may degrade with heat). Thus, electrical conduction occurs via the contact points between the rough surfaces of the transducer element **3100** and the heat sinks, rather than through the epoxy.

Additionally and optionally, parylene or any such suitable coating is disposed on the bonding portion **3310** of the distal heat sink **3300** to act as an additional matching layer. One result of the coating may be to thus produce a second acoustic matching layer for increased efficiency of transducer element **3100** conduction and to further optimize the wide bandwidth performance. The thickness of this parylene coat is ¼ of the target ultrasound wavelength. Optionally, both heat sinks **3200** and **3300** are coated with parylene or any such suitable coatings to provide electrical isolation. Further, heat sinks are anodized to provide electrical isolation while maximizing thermal conduction. The transducer subassembly **3000** is located within a tubular jacket **3400**, as shown in FIG. **5**. The tubular jacket **3400** is a hollow cylinder with a proximal and distal end. The transducer subassembly **3000** is placed into the tubular jacket **3400** such that the distal end of the tubular jacket protrudes a suitable distance, for example between 1 mm to 5 mm beyond the distal end of the transducer subassembly **3000**. The distal end of the tubular jacket **3400** comprises a distal opening **3410**, and fluid exit ports **3420** located near the distal opening. Cooling of the transducer element **3100** may be accomplished by introducing a cooling fluid or gel, such as saline, water, or any physiologically compatible fluid or gel, into the proximal end of the tubular jacket **3400**. The cooling fluid has a lower temperature relative to the temperature of the transducer element **3100**. The cooling fluid flows along the bent portions **3220** and **3320** of heat sinks **3200** and **3300** and over both bonding portions **3210** and **3310** and exits through the distal opening **3410**, the fluid exit ports **3420**, or any combination thereof. Optionally, the exit ports **3420** may be in the form of a grating, a screen, holes, drip holes, a weeping structure, or any of a number of suitable apertures.

Additionally, any or all of the metal components described in transducer subassembly **3000** are provided with a plating of a suitable biocompatible material such as gold. Such plating is provided to the individual components before the transducer assembly is assembled.

In an exemplary embodiment, the temperature of the cooling fluid or gel is sufficiently low that it cools the transducer element **3100** and, optionally, the target tissue. In this embodiment, the temperature of the fluid or gel is between approximately −5 and body temperature. In a second embodiment, the temperature of the cooling fluid or gel is within a temperature range such that it cools the transducer element **3100**, but does not cool the target tissue, and may actually warm the target tissue. The fluid or gel may alternatively be any suitable temperature, including room temperature, to sufficiently cool the transducer element **3100**.

The invention described above has the advantage of keeping the smaller transducer assembly cool. As previously mentioned, the transducer diameter is small enough (less than 0.2 inches, and ideally less than 0.15 inches) to fit into the tip of a catheter and yet generate power density levels that are high enough to create tissue lesions (about 50 watts/cm^2 to 2500 watts/cm^2). This invention keeps the transducer assembly cool in order to create tissue lesions efficiently.

We now turn to describing the formation of lesions. The interaction of the ultrasound beam with the tissue is shown in FIG. **6**. The tissue **276** is presented to the ultrasound beam **272** within a collimated length L. The front surface **280** of the tissue **276** is at a distance d (**282**) away from the distal tip **2110** of the catheter **2000**. As the ultrasound beam **272** travels through the tissue **276**, its energy is absorbed and scattered by the tissue **276**, and most of the ultrasound energy is converted to thermal energy. This thermal energy heats the tissue to temperatures higher than the surrounding tissue. The result is a heated zone **278** which has a typical shape of an elongated tear drop. The diameter D**1** of the zone **278** is smaller than the transducer aperture diameter D at the tissue surface **280**, and further, the outer layer(s) of tissue **276** remain substantially undamaged. This is due to the thermal cooling provided by the surrounding fluid which is flowing past the tissue surface **280**. More or less of the outer layers of tissue **276** may be spared or may remain substantially undamaged, depending on the amount that the tissue surface **280** is cooled and/or depending on the characteristics of the ultrasound delivery system (including the transducer element **3100** the ultrasound beam **272**, the ultrasound energy and the frequency). The energy deposited in the ablation zone **278** interacts with the tissue such that the endocardial surface remains pristine and/or not charred. As the ultrasound beam **272** travels deeper into the tissue **276**, thermal cooling is provided by the surrounding tissue, which is not as efficient as that on the surface. The result is that the ablation zone **278** has a larger diameter D**2** than D**1**, as determined by the heat transfer characteristics of the surrounding tissue as well as the continued input of the ultrasound energy from the beam **272**. During this ultrasound-tissue interaction, the ultrasound energy is being absorbed by the tissue **276**, and less of it is available to travel further into the tissue. Thus a correspondingly smaller diameter heated zone is developed in the tissue **276**, and the overall result is the formation of the heated ablation zone **278** which is in the shape of an elongated tear drop limited to a depth **288** into the tissue **276**.

The formation of the ablation zone (including the size of the ablation zone and other characteristics) is dependent on time, as shown in FIGS. **7A-7D**, which show the formation of the lesion at times t**1**, t**2**, t**3** and t**4**, respectively. As the sound beam **272** initially impinges on the front surface **280** of the tissue **276** at time t**1**, heat is created which begins to form the lesion **278** (FIG. **7A**). As time passes on to t**2** and t**3** (FIGS. **7B** and **7C**), the ablation zone **278** continues to grow in diameter and depth. This time sequence from t**1** to t**3** takes as little as about 1 to 5 seconds, or preferably about 3 to 5 seconds, depending on the ultrasound energy density. As the incidence of the ultrasound beam **272** is continued beyond time t**3**, the ablation lesion **278** grows slightly in diameter and length, and then stops growing due to the steady state achieved in the energy transfer from its ultrasound form to the thermal form balanced by the dissipation of the thermal energy into the surrounding tissue. The example shown in of FIG. **7D** shows the lesion after an exposure t**4** of approximately 30 seconds to the ultrasound beam **272**. Thus the lesion reaches a natural limit in size and does not grow indefinitely.

The shape of the lesion or ablation zone **278** formed by the ultrasound beam **272** depends on factors such as the ultrasound beam **272**, the transducer element **3100** (including the material, the geometry, the portions of the transducer element **3100** that are energized and/or not energized, etc.), any matching layers and/or backings present, the electrical signal from the source of electrical energy (including the frequency, the voltage, the duty cycle, the length and shape of the signal, etc.), and the duration of energy delivery. The characteristics of the target tissue include the thermal transfer properties and the ultrasound absorption, attenuation, and backscatter properties of the target tissue and surrounding tissue. The size and characteristics of the ablation zone **278** also depend on the frequency and voltage applied to the transducer element **3100** to create the desired ultrasound beam.

As mentioned above, properties such as the shape and construction of a transducer element influence the ablation lesions created by the transducer element. The particular example lesion shown in FIGS. **7**A through **7**D is a tear-shaped lesion, for example as produced by a transducer element **3100** comprising a circular disc. A second variation of ablation shape is shown in FIG. **8**, where the ablation zone **278'** has a shorter depth **288'**. In this variation, the lesion **278'** has a more blunt shape than the ablation zone **278** of FIG. **6**. One possible lesion geometry of this second variation may be a tooth-shaped geometry, as shown in FIG. **8**, though the geometry may alternatively have a blunted tear shape, a circular shape, or an elliptical shape. As shown in FIG. **8**, zone **278'** (similarly to zone **278** in FIG. **6**) has a diameter D**1** smaller than the diameter D of the beam **272'** at the tissue surface **280** due to the thermal cooling provided by the surrounding fluid flowing past the tissue surface **280**. This variation in lesion geometry is produced by a transducer **3100***a* having an acoustically inactive portion **4200** located at its center, i.e., a doughnut-shaped transducer which emits an ultrasound beam **272'** that is generally more diffused, with a broader, flatter profile, than the ultrasound beam **272** shown in FIG. **6**. The ultrasound beam **272'** emitted from such a doughnut-shaped transducer, as shown in FIG. **8**, has reduced peak intensity along the midline of the energy beam (as shown in cross section by the dotted lines in FIG. **8**). With this ultrasound-tissue interaction, the reduced peak intensity along the midline of the energy beam is absorbed by the tissue, and less and less of the energy is available to travel further into the tissue, thereby resulting in a blunter lesion as compared to the first variation.

The ultrasound energy density determines the speed at which the ablation occurs. The acoustic power delivered by the transducer element **3100**, divided by the cross sectional area of the beamwidth, determines the energy density per unit time. In the present embodiments, effective acoustic power ranges preferably from 0.5 to 25 watts, more preferably from 2 to 10 watts, and even more preferably from 2 to 7 watts. The corresponding power densities range from approximately 50 watts/cm^2 to 2500 watts/cm^2). These power densities are developed in the ablation zone. As the beam diverges beyond the ablation zone, the energy density falls such that ablation will not occur, regardless of exposure time.

The transducer subassembly **3000** may additionally be coupled to a sensor (not shown). One variation of a sensor is a temperature sensor. The temperature sensor functions to detect the temperature of the surrounding environment, the transducer element **3100**, and/or the temperature of any other suitable element or area. The sensor may also be used to monitor temperature of cooling fluid as it flows past the transducer. The temperature sensor is a thermocouple, but may alternatively be any suitable temperature sensor, such as a thermistor or an infrared temperature sensor. Optionally, the temperature sensor is coupled to the transducer, for example, on the proximal face. Temperature information gathered by the sensor is used to manage the delivery of continuous ablation energy to the tissue **276** during therapy, as well as to manage the temperature of the target tissue and/or the ultrasound delivery system. In one embodiment, the sensor has a geometry that is substantially identical to the geometry of the transducer element **3100**, so that the area diagnosed by the sensor is substantially identical to the area to be treated by the transducer element **3100**. Alternatively, the sensor has a smaller geometry to minimize interfering with the delivery of ultrasound energy, but may be located in a region that is a local hot spot. For example, a small thermocouple mounted in the center of the proximal heat spreader **3200** monitors the temperature at the hottest spot of the transducer assembly. Additional details on temperature sensors are disclosed in applications previously incorporated by reference above.

Alternatively, in a second variation of a sensor, the same ultrasound transducer element **3100** serves as a sensor and is used for the purpose of tissue detection. On the one hand, in order to achieve ablation, the transducer element **3100** is used to generate and deliver an ultrasound beam of sufficient energy to the tissue in a manner such that the energy input exceeds the thermal relaxation provided by the cooling due to the surrounding tissue. This mode of energizing the ultrasound transducer element **3100** is termed as the ablation mode. On the other hand, the transducer element **3100** may be used to image tissue or to detect tissue characteristics, by utilizing an ultrasound signal optimized for tissue sensing which is generally not sufficient for heating of the tissue. One such ultrasound imaging technique is referred to in the art as A-Mode, or Amplitude Mode imaging. This mode of energizing the transducer element **3100** is termed as the imaging mode. The imaging mode is utilized in directing the therapy provided by the ablation of the tissue. The transducer element **3100** can be used in the imaging mode in order to detect the gap (namely, the distance of the tissue surface from the distal tip of the catheter **2000**), the thickness of the tissue targeted for ablation, characteristics of the ablated tissue, the incident beam angle, or any other suitable parameter or characteristic of the tissue and/or the environment around the ultrasound delivery system, such as temperature, thickness and ablation depth. Additional details on these and other applicable features are described in the disclosures previously incorporated by reference.

Additionally and optionally, the ultrasound delivery system of the preferred embodiments includes a processor, coupled to the sensor, that controls the electrical attachments and/or the electrical signal delivered to the electrical attachments, based on the information obtained by the sensor. The processor may be a conventional processor, or it may alternatively be any suitable device to perform the desired processing functions.

The processor receives information from the sensor, such as information related to the distance between the catheter and the tissue (i.e., the gap distance), the thickness of the tissue targeted for ablation, the characteristics of the ablated tissue, or any other suitable parameter or characteristic. Based on this information, the processor controls the ultrasound beam emitted by the transducer element **3100** by modifying the electrical signal sent to the transducer element **3100** via the electrical attachment. This may include modifying the frequency, the voltage, the duty cycle, the length of the pulse, and/or any other suitable parameter. The processor may also control the ultrasound beam in multi-element transducers by controlling which portions of the transducer element are energized, and/or by controlling the frequency, voltage, duty cycle, etc. at which various portions of the transducer element may be energized. Additionally, the processor may further be coupled to a fluid flow controller. The processor may control the fluid flow controller in order to increase or decrease fluid flow based on the detected characteristics of the ablated tissue, of the unablated or target tissue, the temperature of the cooling fluid, tissue and/or energy source, and/or any other suitable conditions. Further, the processor may control the fluid flow controller in order to maintain the transducer element **3100** within a desired operating range of temperatures. Further, the motion of the transducer to create a lesion line or shape in the tissue may be controlled either by an operator or via one or more motors under processor control.

By controlling the ultrasound beam and/or the cooling of the targeted tissue or transducer element **3100**, the shape of the ablation zone **278** can be controlled. For example, the depth **288** of the ablation zone can be controlled such that a transmural or substantially transmural lesion is achieved. Further, the nature of the lesion can be controlled by controlling the speed of the beam. The speed at which the beam moves along the tissue determines the amount of energy deposited in the tissue. Thus, for example, slower speeds result in longer dwell times, thereby increasing the energy transferred to the tissue and, hence, creating deeper lesions. Additionally, the processor functions to minimize the possibility of creating a lesion beyond the targeted tissue, for example, beyond the outer atrial wall. If the sensor detects that the lesion and/or the ablation window is about to extend beyond the outer wall of the atrium, or that the depth of the lesion has reached or exceeded a preset depth, the processor turns off the power generator and/or ceases to send electrical signals to the transducer and/or moves the beam.

Additionally, the processor may function to maintain a preferred gap distance between the transducer and the surface of the target tissue. The gap distance is preferably between 2 mm and 25 mm, more preferably between 2 mm and 20 mm, and even more preferably between 2 mm and 15 mm. If the sensor detects that the lesion and/or the ablation window is about to extend beyond the outer wall of the atrium or is not reaching the outer wall of the atrium, or that the depth of the lesion has not reached or has exceeded a preset depth, the processor may reposition the energy delivery system. For example, as the catheter **2000** is rotated, the ablation window sweeps an ablation path (such as a circular or elliptical ablation path) creating a section of a conical shell. However, if the sensor determines that the ablation window is not reaching the wall of the atrium, the processor may move the elongate member forwards or backwards along the Z-axis, or indicate that it should be moved, in order to adjust for possible variations in anatomy. In such an embodiment, the operator can reposition the catheter **2000**, or the processor may be coupled to a motor drive unit or other control unit that functions to position the catheter **2000**.

While the above transducer elements and transducer subassemblies have been described in the context of ablation catheters, it should be understood that the transducer elements and transducer subassemblies described herein can be used as part of any device configured to ultrasonically image and/or ablate tissue. Additionally, while the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for creating a transmural lesion in tissue, the method comprising:

positioning a distal portion of a catheter near the tissue, wherein an ultrasound transducer is attached to the distal portion and is operatively coupled to a console and processor;

imaging the tissue by energizing the ultrasound transducer at a first power level to produce an ultrasound beam, wherein the imaging determines a thickness of the tissue, and a gap distance between the ultrasound transducer and the tissue;

ablating the tissue by energizing the ultrasound transducer at a second power level to produce the ultrasound beam; and

controlling energy delivered to the tissue during the ablating, using the processor, wherein the processor adjusts a speed of the ultrasound beam moving across the tissue based on the thickness and gap distance, to create the transmural lesion.

2. The method of claim **1**, wherein the ultrasound transducer is energized at a first frequency level during the imaging and a second frequency level while ablating.

3. The method of claim **1**, wherein there is no direct contact between the ultrasound transducer and the tissue during imaging or the ablating.

4. The method of claim **1**, wherein the transmural lesion has a tear drop shape.

5. The method of claim **1**, wherein during the ablating, the transmural lesion is created while an outer layer of tissue remains substantially undamaged.

6. The method of claim **1**, wherein during the ablating, the transmural lesion is created while an endocardial surface of the tissue remains uncharred.

7. The method of claim **1**, wherein the ultrasound transducer comprises a single, flat transducer element.

8. The method of claim **7**, wherein the ultrasound transducer comprises an inactive portion surrounded by an active portion.

9. The method of claim **7**, wherein a heat sink is attached to the ultrasound transducer.

10. The method of claim **7**, wherein a matching layer is coupled to the ultrasound transducer.

11. The method of claim **1**, wherein the processor further adjusts a catheter position to maintain a preferred value for the gap distance during the ablating.

12. The method of claim **1**, wherein the processor further adjusts a catheter position to achieve a preset depth for the transmural lesion.

13. The method of claim **1**, wherein the processor indicates to an operator to reposition the catheter for the ablating.

14. The method of claim **1**, further comprising supplying a cooling fluid in fluid communication with the ultrasound transducer.

15. The method of claim **14**, wherein a temperature sensor is coupled to the ultrasound transducer for monitoring temperature of the ultrasound transducer.

16. The method of claim **14**, wherein the processor controls flow of the cooling fluid to maintain a temperature of the ultrasound transducer within a desired operating range.

17. The method of claim **14**, wherein the processor controls flow of the cooling fluid based on detected characteristics of the tissue.

18. The method of claim 1, wherein the processor, based on the thickness and the gap distance, controls the ultrasound beam by modifying an electrical signal sent to the ultrasound transducer.

19. The method of claim 1, wherein the processor uses the speed, the energy delivered, and a beamwidth of the ultrasound beam to deliver a desired energy density to the tissue.

20. The method of claim 1, wherein the imaging further comprises determining an incident beam angle, and the incident beam angle is used to determine the speed of the ultrasound beam during ablation.

21. The method of claim 1, wherein the second power level is different from the first power level.

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